



Pricing for survival

**As demand for pharmaceutical
cost containment intensifies,
novel drug-pricing approaches
are critical**



The pharmaceutical industry has traded one major challenge for another



First, an unprecedented number of blockbuster drugs came off patent over the last decade, and manufacturers were not able to pump out new drug innovations fast enough to replace them. The result was that sales and profit growth for most major pharmaceutical companies fell from double digits to low single digits. Although many masked these growth woes with aggressive M&A activity and consolidation, coupled with significant year-on-year price increases for blockbuster brands in the United States, the overall outlook was disheartening.

In the interim, there has been some good news: Pipeline productivity returned with regulatory approvals of new molecular entities (NMEs) that equal, or even surpass, launches during the boom times of the 1990s. The difference now is that most of these NMEs are specialty pharmaceuticals – medicines that target much more complex disease states with smaller patient populations than the blockbuster drugs of yesterday. And among these specialty drugs, nearly half are for rare or orphan disease populations, with another 25 percent for diseases that, while not necessarily rare, are complex enough to require management by sub-specialists within fields such as immunology, oncology, neurology, endocrinology, and cardiology.

The research and development for these drugs is astronomically high – an average of \$2.6 billion per product, according to recent estimates.¹ In order to recoup costs, manufacturers bring these drugs to market at a cost per patient that has skyrocketed from hundreds of dollars to tens of thousands a year. In oncology, it is now common to see the annual price of drug therapy surpass the \$100,000 mark. And, in certain orphan disease spaces, the price point can be from \$200,000 to \$500,000. It is, therefore, not surprising that, although they represent only 12 percent of prescriptions, specialty drug sales account for 72 percent of total drug spending, according to the AMA.²

Enter challenge number two: Historically the concept of unmet need trumped everything. Private and public payers were willing—or had no other option than—to pay high prices. The diseases being treated were so severe and patient numbers were so small that any single high-priced specialty therapy had only a minimal financial impact on the overall pharmacy budget.

In the current environment, this is no longer the case. With the explosion of hyper-priced specialty drug therapies, many of which are used as part of combination therapies targeting complex disease pathways, drug pricing has come under intense payer scrutiny. Payers have the leverage to exert downward pressure on pricing for drugs that were often under the control of physicians and hospitals. The reason for this change? Drug manufacturers tend to hunt in packs, i.e., follow scientific developments—often originating in academic labs and publicly funded research institutions—in parallel, and develop similar drug innovations within the same indications. This leads to multiple drug therapies within a single drug class that payers can choose from, even in rare disease spaces.

While this dynamic is not entirely new, the impending specialty drug budget crisis is causing payers to take more aggressive action on pricing in ways never imagined by pharmaceutical manufacturers. Payers are using competitive dynamics to garner discounts and rebates in disease states where contracting for volume was previously the rare exception. However, list price discounts are just the start. Payers in developed markets across the globe are increasingly using price control mechanisms, as allowed by their national healthcare policy frameworks, to force price cuts annually or whenever a drug is approved for a new indication. Further, payers are increasingly relying on versions of *winner-takes-all* contracting, awarding near exclusive access to the lowest-priced agents when efficacy is comparable.

When managing price directly isn't possible, payers can in some cases limit access to therapies, even in disease spaces where physician preference was historically considered sacred. For example, some private payers in the U.S. now offer incentives to healthcare providers to favor certain oncology and immunology drugs. And, based on the guidance of medical community opinion leaders, payers of all types are even exercising their influence on the sequence or combinations of drugs used within complex treatment protocols.

These dynamics have awakened pharma players to the fact that the current approach to specialty pharmaceutical pricing is unsustainable. The days of demanding steep innovation premiums simply because a disease state was rare or complex are numbered or already gone. Most drug developers today recognize that the solution to payer scrutiny are pricing models that effectively and transparently connect drug prices to value. Of course, it is challenging to pursue new pricing models while continuing to offer *beyond the pill or infusion* services that patients and their providers need to improve outcomes. Unfortunately, introducing a more effective and transparent pricing model has, at least so far, proven challenging.

In order to help pharmaceutical manufacturers devise drug-pricing and patient-access strategies in such a challenging environment, this paper covers:

- The clash between payer and manufacturer perspectives when it comes to pricing, reimbursement and patient access
- The reasons why full outcomes-based pricing, or value-based contracting, is not yet viable
- An in-depth look at the interim pricing models manufacturers can pursue today
- A guide to what organizations should do first in the evolution toward more fair and transparent pricing

Conflicting perspectives— payers vs. drug companies

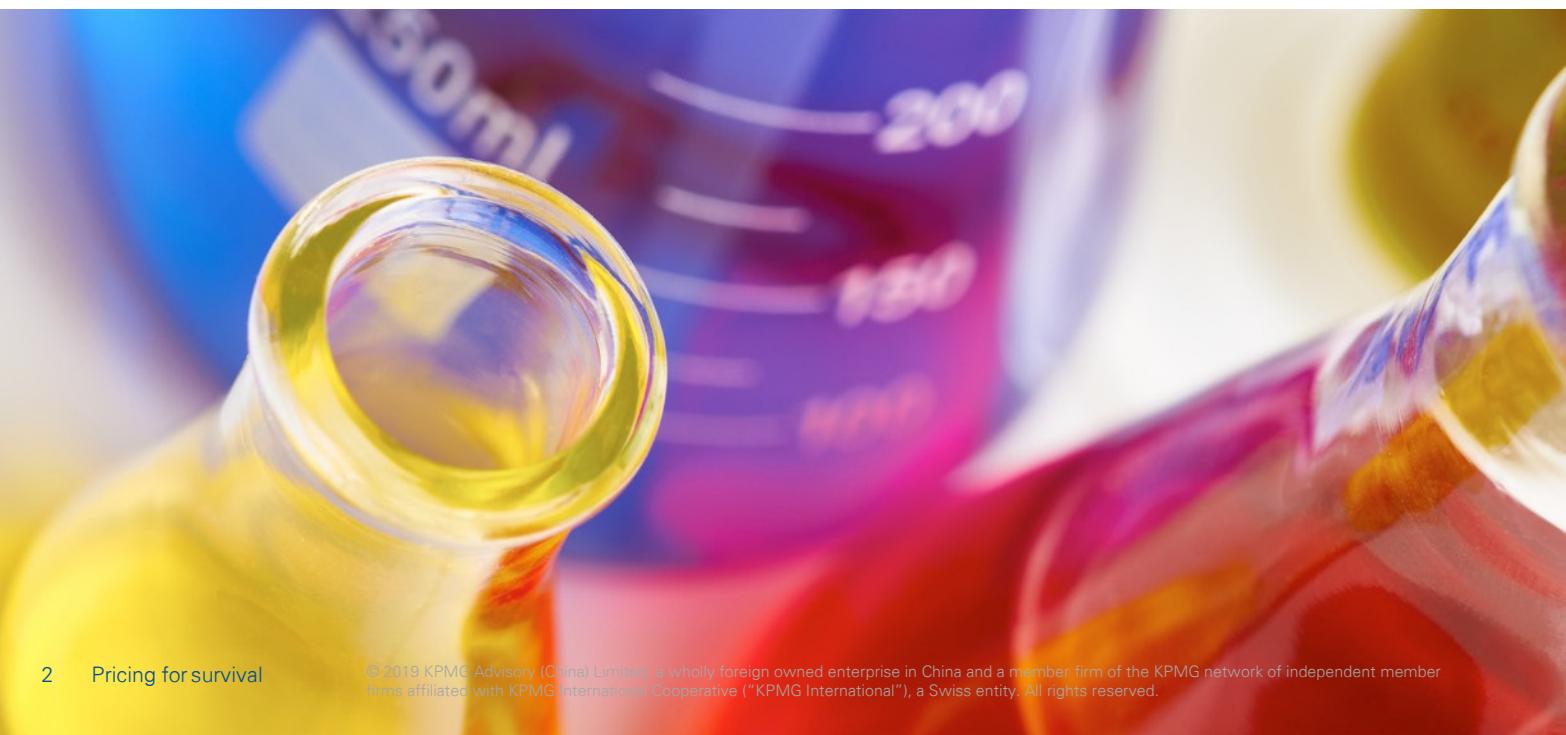
Across the globe, there are several major forces colliding as payers rethink how to manage healthcare costs, including drug spend. In the US private sector, the need to take costs out of the healthcare system has led to consolidation among providers to achieve economies of scale. In the public sector, policymakers are evaluating drug costs vs. benefits and demanding more uniformity in how physicians prescribe drugs for particular types of patients.

In Europe, the focus on cost reduction by national and regional health systems has led to tighter drug pricing and restriction of patient access through more stringent health technology assessment (HTA) methodologies. The latter are designed to link pricing for new innovations to how much added benefit the products offer over current standards of care. The bottom line is, payers today have much greater leverage to negotiate prices and demand significant improvements from any new drugs for which they choose to reimburse.

Among manufacturers, most realize that new innovations must achieve greater alignment between price and the value offered to patients. However, the knee-jerk reaction to pricing pressure has often been to raise the possibility of *outcomes-based pricing*, otherwise known as pay-for-

performance or value-based contracting. And there were 25 drugs engaged in various types of outcomes-based arrangements with payers in the fragmented United States market as of September 2017, according to a study from the Commonwealth Fund.³ The problem is, these models appear to be limited in applicability to disease states with more standardized protocols and dominated by drug therapies with single indications—notably osteoporosis, diabetes and hepatitis C. To date, outcomes-based pricing models seem to be most appealing to payers that are fully integrated with healthcare delivery (i.e., closed-loop payer-provider health systems or integrated delivery networks).

In Europe, particularly in the United Kingdom and Italy, government payers have engaged with the pharmaceutical industry in risk-sharing agreements. Most prevalent in oncology, these agreements attempt to cap payer cost exposure by basing prices primarily on whether drug therapies work or not. However, these models have proven to be either too complicated to administer or no closer to connecting drug pricing to value than typical discounts and rebates. The takeaway is that, when it comes to specialty and orphan drugs, outcomes-based pricing simply faces too many barriers at present. (For details of barriers to outcomes-based pricing, see next two pages.)



Barriers to outcomes-based pricing:

– **Technology and data infrastructure hurdles** – On the one hand, the plethora of big data from patient registries, user-friendly patient-reported outcomes tools, social media platforms, the Internet of Things, and electronic health records (EHRs) should make quantifying outcomes more viable. Yet, pharmaceutical manufacturers have not yet mastered how to access real-world evidence (RWE) that speaks to efficacy and economic value on an on-going, real-time basis – a requirement that goes way beyond the clinical data ordinarily derived from research and development. And it has also not yet been determined whether it is more appropriate for manufacturers or payers to take the lead on data collection and analysis, not to mention the cost of managing outcomes data over time.

– **Patient privacy restrictions** – Outcomes-based pricing models in their purest form attempt to link drug pricing to the actual treatment results realized by individual patients. That means patient-level data must be not only collected and analyzed, but protected. Patient privacy has always been an issue in healthcare, but the use of patient data needed for outcomes-based pricing could be dramatically restricted by the introduction of the General Data Protection Regulation (GDPR). The new law was introduced in Europe this year and, in addition to impacting the European operations of multinational corporations, the law's data restrictions will soon make their way to the U.S. So until the scope of how pharma companies can use patient data is determined, there will be some risks in going too far down the outcomes-based payment path.

– **Unclear incentive structures**

– Although manufacturers view outcomes-based payments as a way to differentiate themselves from the competition, payers aren't equally motivated to embrace this model. It is still too easy to leverage competitive dynamics to extract discounts. Moreover, the added cost and administrative complexity of managing unique pricing arrangements for each drug is often a non-starter for payers as they continue to feel the pinch of shrinking budgets and resource constraints.

Investing in real-world evidence today for more transparent pricing tomorrow

As the life sciences industry focuses more and more on both rare diseases and personalized medicine, recruiting an adequate sample population for clinical trials will be difficult enough. Using clinical trial evidence to extrapolate from short-term findings to long-term benefits is almost impossible. Instead, pharmaceutical manufacturers will increasingly need to rely on real-world evidence (RWE) to assign value to these treatments. Value in this case will include not only how well a drug works, but whether it improves quality of life and lessens the burden of an illness.⁴

Getting to the level of analysis required to quantify the value of real-world evidence for treatment protocols – as a whole and for each of their component parts – is enormously complex. Therefore, manufacturers should be investing significant time and resources to explore the issue. Since organizations won't have much control over how a drug is used once it's in the system, this analysis has to look at different scenarios and how each would be reimbursed. Ultimately, the goal is for the entire medical establishment to work in concert to solve for inefficiencies in the system that hinder collection and analysis of RWE.

The benefits of interoperability

Regulations on which the industry has been basing some of its assumptions about outcomes-based pricing are currently in a state of flux. For example, the industry is spending quite a bit of effort conforming to the requirements of the Drug Supply Chain Security Act (DSCSA), which mandates that drug supply chain participants and the FDA track products via an interoperable system by 2023. Over time, such efforts will play a role in outcomes tracking by connecting specific drugs to particular patients. However, such capabilities are years away from becoming a reality.

- Outdated regulations – The regulatory environment governing the interactions between pharmaceutical manufacturers and payers often presents challenges when designing outcomes-based contracts. While payers may see value in using outcomes-based payments for high-priced drugs, the specific types of end-points on which they would like to base these agreements are often not studied in clinical trials. More often than not, unless the data is on the product label, it cannot be the basis for contracting. Moreover, manufacturers who offer products for free—or dramatically discounted prices when they fail to achieve agreed-upon outcomes—face the risk of getting caught up in regulations that ensure certain government payers receive the most favorable discounts (e.g., Medicaid “best price” rules in the U.S.) or a guarantee that patients will receive equal access to approved drug therapies.

- Disparate types of payers – Delivering on the promise of outcomes-based pricing is not a *one-size-fits-all* exercise because of the disparity between payers and their approaches to determining reimbursement policies. Payers across the globe have distinctly different healthcare budget priorities. Even defining what *value* means for a given drug therapy is a subject of debate, and the definition can vary depending on the type of payer in question. This means scaling outcomes-based contract designs across countries could be difficult, if not impossible, for manufacturers. Imagine a world in which an individual drug is subject to a different outcomes-based pricing model in each country market, with each regional payer, or even with each hospital budget holder. The complexity would be mind-boggling for even the most sophisticated pharma players.



The compromise

Instead of leapfrogging to outcomes-based pricing prematurely, manufacturers can take more practical steps toward ensuring that drug pricing reflects the value delivered. First, since most drugs tend to work in more than just a single indication, pharma players must be able to isolate how a particular drug delivers value across the several potential disease states and patient sub-populations in which it may be efficacious. Second, given that drugs aren't often used in isolation to treat diseases, manufacturers must also parse out the mechanism by which the drug delivers value versus other drug and non-drug factors (e.g., devices, diagnostics) in the therapeutic mix. Finally, pharmaceutical innovators must achieve greater transparency into what component contributes what portion of an outcome – and what may be getting in the way. Other ancillary considerations include direct medical interventions, care- coordination technologies, best practices for care delivery, and other solutions that shape the patient experience.

These are no small tasks. However, pharmaceutical players have the opportunity to start tackling these steps toward outcomes transparency by moving forward with approaches to pricing for value that don't require wholesale changes in the system. The following three approaches that pharmaceutical manufacturers are using today warrant further exploration:

1 Pay-by-use strategy or indication-specific pricing

What is it? With indication-specific pricing (ISP), drug prices are defined at the indication level based on the clinical and economic value the drug provides over the existing standard of care. The objective is to align what is paid with what is delivered so that innovation is fairly rewarded at any point in the lifecycle.

What are the factors that led to this approach? A stepping stone to outcomes-based pricing, ISP involves setting different prices for different indications or for different patient sub-populations within the same broader indication. At present, the vast majority of healthcare systems globally do not adequately address the fact that a single pharmaceutical innovation can deliver value in different ways. The *one-drug-for-one-price* model is increasingly leading to cost inefficiencies, whereby payers are reimbursing a drug to the same degree across indications, regardless of the level of therapeutic benefit. Even more inefficient, when a follow-on indication requires ten times the dose of the lead indication, payers could be left holding the bag for a ten-fold increase in price.

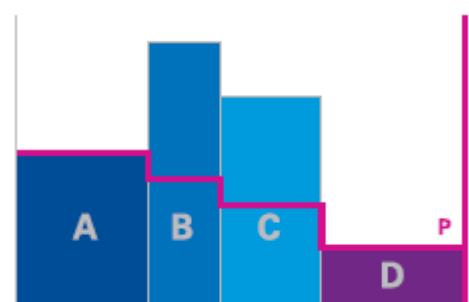
Typical Trajectory of Lifecycle Pricing



A gross price, often based on existing drug benchmarks, is typically established for the lead indication, but declines over time due to increased volume uptake with indication expansion.

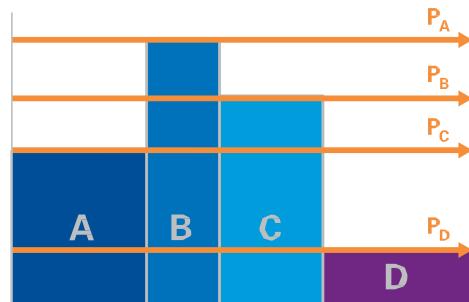
Note: "P" Price

Likely Future Trend for Lifecycle Pricing



Payers are becoming more aggressive about managing price as volume grows through indication expansions. In major markets, this often translates into significant reductions in net price over time, often in line with the value delivered by subsequent indication.

The Benefits of ISP on Lifecycle Pricing



ISP allows for a more value-oriented approach to preserve price for subsequent indications.

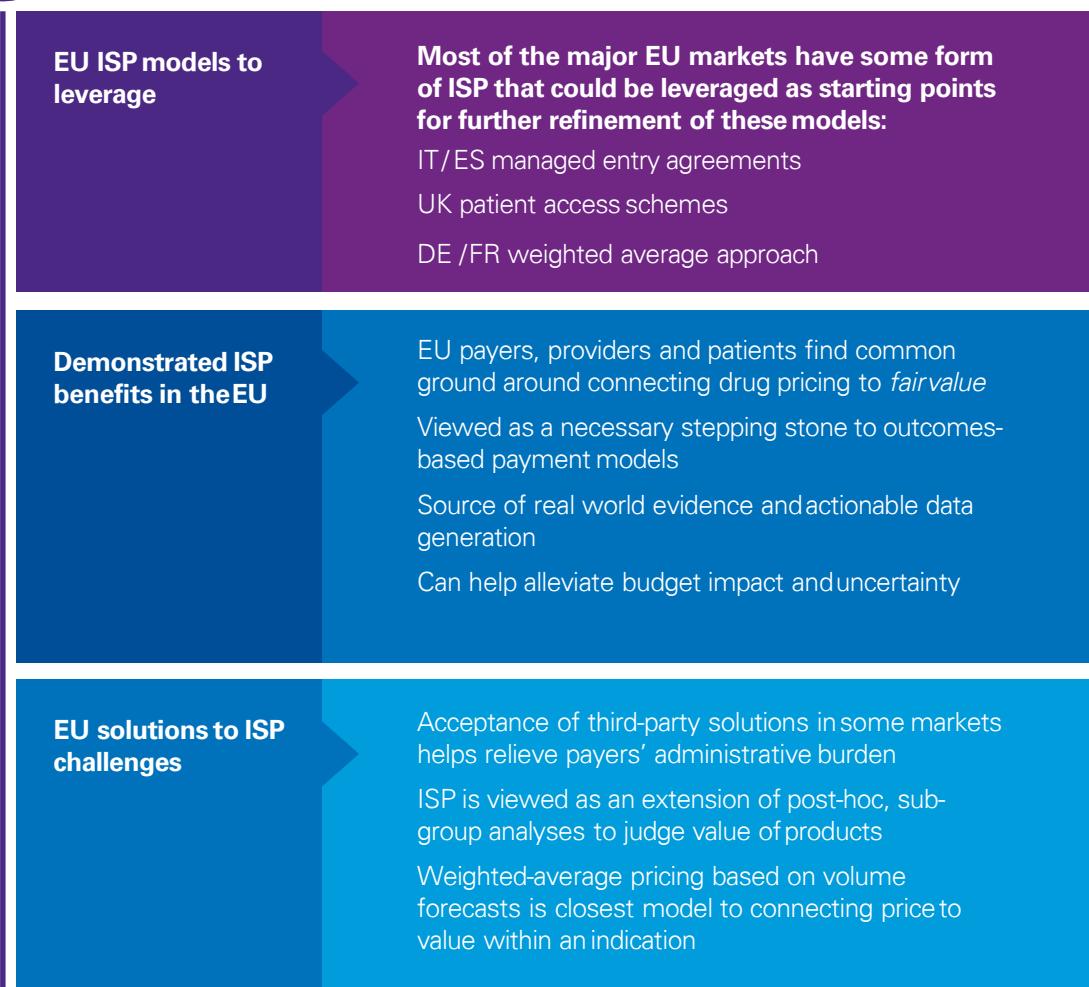
Pay-by-use or indication-specific pricing (continued)

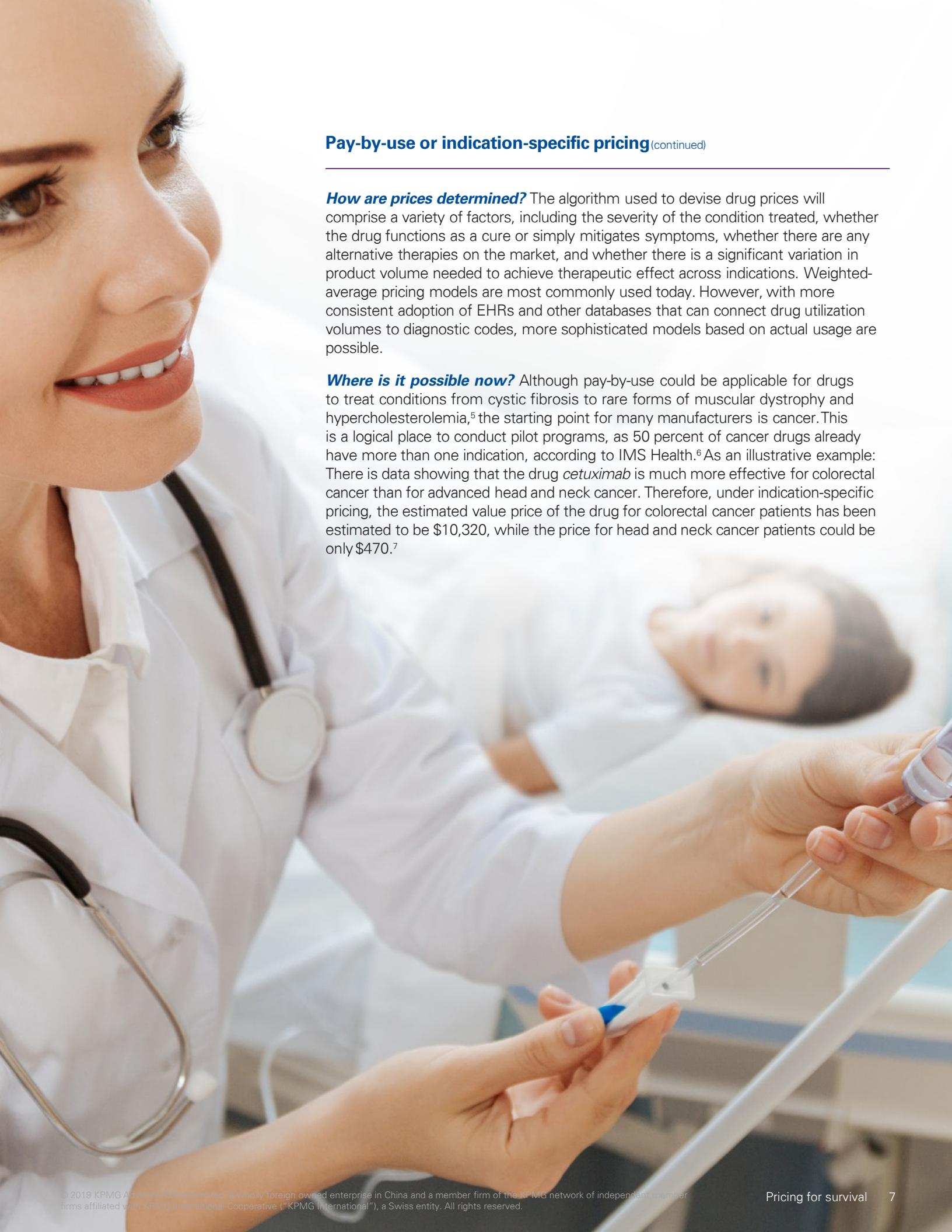
Recognition by payers of these inefficiencies is not new. ISP is more established in Europe, where most healthcare industry players acknowledge that there should be a way to reflect the fact that multi-indication drugs can offer superior outcomes for one condition and only marginally better outcomes for another. Weighted-average pricing

models, which account for distinct prices and projected drug utilization by indication, aren't perfect. Yet such models offer a starting point for discussions about linking pricing to value, which will be fundamental to future outcomes-based arrangements.



ISP Lessons from the EU: Why Invest?





Pay-by-use or indication-specific pricing (continued)

How are prices determined? The algorithm used to devise drug prices will comprise a variety of factors, including the severity of the condition treated, whether the drug functions as a cure or simply mitigates symptoms, whether there are any alternative therapies on the market, and whether there is a significant variation in product volume needed to achieve therapeutic effect across indications. Weighted-average pricing models are most commonly used today. However, with more consistent adoption of EHRs and other databases that can connect drug utilization volumes to diagnostic codes, more sophisticated models based on actual usage are possible.

Where is it possible now? Although pay-by-use could be applicable for drugs to treat conditions from cystic fibrosis to rare forms of muscular dystrophy and hypercholesterolemia,⁵ the starting point for many manufacturers is cancer. This is a logical place to conduct pilot programs, as 50 percent of cancer drugs already have more than one indication, according to IMS Health.⁶ As an illustrative example: There is data showing that the drug *cetuximab* is much more effective for colorectal cancer than for advanced head and neck cancer. Therefore, under indication-specific pricing, the estimated value price of the drug for colorectal cancer patients has been estimated to be \$10,320, while the price for head and neck cancer patients could be only \$470.⁷

Pay-by-use or indication-specific pricing (continued)

What is the primary issue(s) the industry has to solve in order to scale this solution? In each case, manufacturers will have to determine whether it makes more sense to bring a drug to market for the lower- or higher-priced indication first. Bringing a product to market for the indication with the greatest chance of making a positive impact on clinical outcomes will show an earlier return on investment and, thereby, pave the way for research into other applications for the same drug.

There are several things manufacturers should watch out for here to ensure that indication-specific pricing isn't undermined before it even takes hold. For example, if two

prices for the same drug are available in the marketplace, purchasers may be tempted to purchase the drug at the lower price with the intent of using it for the indication that merits a premium price. Further, if manufacturers abuse the system by reintroducing mainstream drugs for one orphan disease after another, they run the risk that the FDA will set stricter parameters on how drugs can be prescribed for more than one condition.⁸

Aspects of indication expansion that impact price optimization



Follow-on indication economic variables

- Patient population size
- Dose magnitude
- Therapy duration
- Single agent vs. combination use



Follow-on indication clinical variables

- Level of unmet need
- Performance relative to indication SoC
- Clinical and price benchmarks
- Robustness of data package

2 Combination therapy pricing

What is it? Combination therapy pricing is a framework for bundling the costs of different aspects of a multi-drug protocol, effectively ascribing value to how each of the components contributes to outcomes and distributing payments according to that value.

What are the factors that led to this approach? More and more, a drug's value can't be quantified on its own. As scientists discover diseases that are caused by multiple factors, it is more critical to intervene in the disease process at more than one point in the pathway, i.e., with combination therapies involving two or more drugs. The challenge is, as many of these protocols comprise breakthrough drugs, combinations can be priced at \$100,000 to \$300,000 per patient per year.

How are prices determined? The most difficult aspect of this approach will be coming up with an algorithm to determine which drug in a combination therapy protocol offers the most value. Said value is influenced by whether one or both agents in the combination are new, serve a well-established existing market as monotherapies or part of other combinations, and will remain patent-protected for a significant length of time.⁹ Of course, the question is further complicated by the likelihood that the drugs come from different manufacturers. A single manufacturer negotiating pricing for a proprietary combination of its own drug assets is relatively simple compared to arbitrating disputes on pricing and value between manufacturers.

Combination pricing hurdles to overcome

Incentives for payers to adopt new combination-pricing approaches are low, as illustrated below. Therefore, manufacturers must take the lead on tackling these hurdles and driving meaningful change.



Measuring Value

Lack of evidence to quantify relative value contribution of combination components: Current evidence generation does not allow manufacturers to demonstrate value allocation for each compound, notably when there are synergistic effects.



Ascribing Value

Lack of payer motivation to ascribe differential value: Payers have been more interested in the overall outcomes and cost of a combination than in the incremental value of each molecule.



Sharing Value

Manufacturers reservations about sharing value: There are no mechanisms, guidelines or regulations in place governing sharing of value among different compounds and companies. And backbone owners have no incentive to accommodate add-ons.



Key Insight:

In the absence of manufacturers pushing for viable price-to-value mechanisms for combination therapies, payers are likely to cling to the status quo of demanding price concessions.

Combination therapy pricing (continued)

Where is it possible now? Until recently, cancer has been the model for combination therapy. However, outcomes from chemotherapies are relatively simple to measure, and the drugs aren't very expensive. As we go forward, there will be a burgeoning need to develop pricing protocols for expensive combination therapies in complex disease states, certainly within oncology, but also in other areas like immunology and rare neurological disorders where different mechanisms may be required to delay disease progression.

What is the primary issue the industry has to solve in order to scale this solution? Advanced data and analytics have given organizations the opportunity to use quantitative

modeling to predict how different pricing strategies could play out, uncover the set of conditions that could make one pricing strategy superior to another, and determine the risks of each path taken.¹⁰ Optimizing the pricing strategy for a proprietary combination using these methodologies is already possible. However, applying these principles to the more likely scenario that combination therapies span multiple manufacturers, and may include drug therapies that are at different points in their lifecycles, is a hurdle that must be addressed.

External vs. internal strategies

Pursuing Novel Pricing & Collaboration Models with External Partners

This is a winning strategy when...

- Combination portfolio assets have such strong clinical profiles that backbone partners are compelled to collaborate.
- Payers can be convinced to deviate from the traditional price-reduction paradigm by the value of the combination.
- Regulators see value in easing restrictions on manufacturer collaboration to reduce overall healthcare costs.
- Healthcare IT and other implementation issues can be overcome through cooperation between manufacturers and payers.

Managing Combination-Drug Portfolio Internally

This is a winning strategy when...

- First-in-class or best-in-class backbone therapies that establish price benchmarks can't be challenged by follow-on combination agents.
- The R&D pipeline nets a sufficient diversity of MOAs to ensure a continuous flow of internal novel-novel combinations, eliminating the need to partner externally.
- Payers continue to prefer the simplicity of the price reduction model and resist multi-manufacturer pricing collaborations.
- Regulations governing pricing negotiations aren't adjusting quickly enough, putting multi-manufacturer combination-pricing arrangements at higher risk for price collusion violations.

Adapting a combination pricing strategy to your portfolio model: Questions to ask yourself



The Multiple-Manufacturer Dilemma

When different manufacturers own different components, the price of the regimen should be allocated across all medicines, irrespective of which product launched first. However, payers lack the tools to execute on this vision.

- How can we manage pricing of two agents given regulatory restrictions on pricing collaborations?
- What level of exclusivity should be demanded of external partners?
- How can we share value with other manufacturers in a compliant manner?



The Backbone Dilemma

Complexity is further compounded by which manufacturer owns the backbone and which owns the add-on, whether the combination indication is the first use of the drugs or a follow-on indication, and whether any of the products is approaching the end of patent exclusivity.

- How can we identify and structure a deal with the optimal backbone partner?
- Should we wait for an internal backbone rather than partnering externally?
- How can we increase our negotiating leverage with the external backbone partner?



The Home-Grown Dilemma

While proprietary combinations offer greater pricing control than multiple-manufacturer combinations, they present their own challenges related to the robustness of the product profile and the durability of competitive differentiation.

- Are we putting the best combination assets forward?
- How can we stage and prioritize single-agent and combination therapies to optimize pricing and market access?
- How can we leverage the benefits of a single identity for the combination to maximize commercial value?

3 Product-to-patient strategies

What is it? Otherwise known as patient and healthcare provider (HCP) support programs, product-to-patient strategies address a broad array of factors, such as healthcare stakeholder needs insofar as they impact medication adherence, understanding of care-delivery protocols, and availability of transportation to physician appointments and treatments. This approach recognizes that value can derive from everything that comprises the care continuum – from optimal site of care, to evidence-based medical interventions, to care progression, to the medical devices that are used, to the drugs that are prescribed and the order in which they are administered.

What are the factors that led to this approach? Putting the patient at the center of decision-making is becoming a requirement as healthcare becomes increasingly consumer-driven. Therefore, before the medical industry can even begin to explore outcomes-based drug pricing, all players must address major inefficiencies in how, where and when patients are treated. After all, direct pharmaceutical treatments are not the only factors that

contribute to patient outcomes, as past *beyond the pill* offerings illustrate. Just as critical are efforts made by healthcare systems and their innovation partners, which include pharmaceutical manufacturers. These include patient support programs focused on adherence and care redesign efforts to ensure that patients can access the right care at the right place and the right time.

How are prices determined? The first step in aligning drug prices with a holistic approach to patient care is addressing care settings that are fragmented and unable to coordinate data sharing. Eventually drug utilization will need to be tied to complex pricing analyses comprising diagnoses, hospitalizations and other care events.

Where is it possible now? Although oncology may be making the fastest headway into creating evidence-based treatment protocols that fold medication decisions into the broader context of care redesign, it is easy to see how this might be applied in other specialties, including immunology, hospital-based infectious diseases, and heart failure.

The evolution from traditional *beyond the pill* services to true *product-to-patient* offerings



The Past: Foundational Solutions

- General information on product characteristics, access and proper use
- Static and passive resources requiring HCPs and patients to search for information
- Answers to one-time questions with low ongoing engagement
- Similar patient experience, regardless of the product or disease state



The Future: Innovative Solutions

- Resources and material that address emotional, social, economic aspects of condition
- Dynamic & proactive in anticipation of patient needs
- Tailored to individual situations, requiring opt-in for full participation
- Evolves over lifecycle with changing patient needs and market dynamics
- High level of engagement and continuity of interaction
- Unique look and feel by brand

Product-to-patient strategies (continued)

What is the primary issue the industry has to solve in order to scale this solution? There must be widespread adoption by clinicians of evidence-based standards of care for targeted diagnosis-related groups (DRGs). Ultimately, care pathways should prescribe daily medical milestones, treatment patterns, anticipated lengths of stay, recommended tests, and the most appropriate pharmaceutical treatments – all of which will contribute to varying degrees to desired clinical outcomes.

Product-to-patient models by patient/provider need

New Treatment Ramp-Up Programs	Healthcare Provider Care-Delivery Support (Traditional/ Alternative)	Access and Reimbursement Navigation	Patient-Motivation Programs	Patient-Adherence Support
Digital and in-office resources explaining value proposition and addressing barriers to adoption	Support for the procurement process, choosing the procurement model, and ordering the drug	Educational materials on reimbursement, coding, billing, and procurement for medical benefit	Online resources to illuminate expectations of disease journey, gauge treatment impact, and articulate benefits of treatment on outcomes/ quality of life	Educational materials, e.g., guide to treatment schedule, implications of lack of adherence, strategies to improve adherence, etc.
HCP and patient testimonials on the treatment experience	Guides/ videos on drug administration, nurse educators who train staff to prepare, administer, and code and bill for drug	Self-service tools, e.g., online coverage database, financial assistance and program enrollment support	Patient self-monitoring and planning tools, e.g., online symptom and outcome trackers, printable goal-setting / treatment-planning tools	Treatment management tools, e.g., office and alternate site locator, printable calendars, treatment planning tips, broader disease management resources
HCP engagement tools, e.g., online prescriber locator, guide to patient conversations	Educational guides on drug storage, patient scheduling tools	Patient financial support, e.g., OOP assistance	Virtual patient community that is branded, opt-in, online, and peer-to-peer to enhance emotional connection to treatment and share experiences	Self-reported appointment tracker with reminder push notification services via online portal or app
Patient-focused starter kit and virtual support for self-administered treatments	Troubleshooting hotline to address site challenges as they arise	Reimbursement support hotline	—	Troubleshooting hotline for issues with therapy continuity

Patient and provider inflection points for introducing *product-to-patient* offerings

Patient situation

- Significant daily disease burden, often with multiple co-morbidities
- Treatment progress can be tracked and assessed via measurable symptoms
- Availability of multiple alternative treatments and/or viability of no treatment
- Competitive intensity driving considerable variation in formulary coverage and/or patient OOP burden
- High level of anxiety around administration, AE profile of new therapy
- Prevalence of frequent medication cycling among competing drugs

HCP situation

- Significant administrative complexity associated with new treatment approach vs. standard of care (e.g., shift in reimbursement model, drug delivery requirements)
- Major shift in the treatment paradigm beyond mechanism of action or route of administration (e.g., Botox in migraine prophylaxis)
- Desire to opt-out of administration and refer patient to alternative site of care due to lack of capacity or practice economics

What manufacturers can do right now



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Engage with payers over time: Manufacturers should commit to a long-term, two-way dialogue with payers with the goal of refining indication-specific pricing models for mutual benefit.

Develop real-world evidence: With the proliferation of social media platforms, the Internet of Things and electronic health record (EHRs), gathering evidence of a drug's efficacy for real-world patients has become more viable. All indications are that payers are open to real-world evidence (RWE), as evidenced by a recent study from the International Society of Pharmacoeconomics and Outcomes Research.¹¹ Seventy-eight percent of payers surveyed said they "sometimes" consider RWE in Rx policies, and they do so most frequently when it comes to formulary placement and utilization management.

Share the most compelling evidence: Manufacturers should participate in the industry-wide discussion about how to define a drug's success, e.g., lower total cost of care, less off-label usage, etc.; undertake contract design pilot programs; and share lessons learned industrywide.

Conduct population-health studies: Both payers and manufacturers need to study and gain greater transparency into how patients are caring for themselves, the barriers to full medication adherence, what types of patients are embracing outpatient and home-based care settings versus hospitals, etc.

Develop business cases: Since determining when indication-specific pricing will have the most business benefit is a complicated process, manufacturers should invest in pilots as opportunities emerge and incorporate ISP into portfolio-planning processes.

Begin thinking about communication issues: Both internal and external communication will be critical as manufacturers move toward ISP and other new pricing models: As prices are determined, payers and manufacturers should consider how best to communicate the rationale to purchasers, especially if the price will result in higher cost-sharing for patients or new administrative requirements for providers (e.g., prior authorization). Some providers may balk at having to assume the administrative burden of tracking patient usage by indication, but they should understand that, ultimately, this approach will lead to more detailed documentation of outcomes and richer data on healthcare encounters.¹²

Lobby for policy change: The pace of change toward indication-specific pricing, and ultimately outcomes-based pricing, would accelerate if policies were in place to support it. The life sciences industry should be communicating with Congress to encourage policy initiatives that alter drug reimbursement models, eliminate the impact of the Medicaid Best Price model on ISP, and enable indication-specific patient cost sharing. Further, organizations should stay abreast of the efforts of high-level academic consortia, including the Economic Strategy of Pharmaceutical Products department of AIFA.



Conclusion

Our hope is that this paper is a starting point from which organizations can take steps toward drug and healthcare pricing that offer fair value to all parties. From the manufacturers' perspective, if there is more granularity of pricing for each indication, it is likely that drugs will be approved for more indications. From the payers' perspective, achieving clarity on pricing will make it easier to fund high-value innovations, which in turn could drive good will for the industry. And for providers and patients, connecting drugs and treatments to particular conditions will generate valuable patient data that can be used to target underserved populations, create new drug innovations, and raise the quality of healthcare overall.

How KPMG Can Help

KPMG helps pharmaceutical companies weigh market access strategies in terms of feasibility and priority, integrate payer perspectives into R&D and commercial processes, anticipate and react to developments by commercial and government payers, and ensure that products are well-positioned and supported by robust evidence of meaningful outcomes for cost. We work with companies on transforming the way they approach market access, new product development and portfolio management

through our *Nine Levers of Value* methodology connecting business model design (strategy) and operating model implementation (execution). With senior practitioners dedicated to data & analytics, R&D and commercial strategy, regulatory affairs, risk consulting, and M&A advisory, our *one firm* approach to client engagements results in an enterprise-wide view from strategy through results.

The process:

- Start with a diagnostic of client's level of exposure to payer pressure, as well as appetite for a different approach to pricing.
- Identify the top challenges to address based on the nature of the portfolio and types of pressures an organization faces.
- Form task forces that blend cross-functional expertise.
- Implement new approaches to pricing and market access with payers at global, national, regional and local levels.
- Assist with payer negotiation, dedicating specialized resources to handle specific issues and address administrative complexity.
- Dedicate resources to managing partnerships within and across the industry, e.g., IMS database development consortia, trade associations and policy influencers.
- Manage partnerships with third-party providers of services required to support ISP administration.

About the authors

Peter Gilmore, Principal in KPMG Strategy, has more than 15 years of experience advising senior management teams at leading pharmaceutical, medical device, and consumer health companies. Peter supports life sciences clients on both transformation and optimization engagements, focusing on commercial and R&D issues related to resource portfolio management, commercial model innovation, market access, contracting, product development, and launch planning. He has evaluated numerous licensing and acquisition deals across 30+ disease categories, using advanced valuation models and decision analysis methodologies. Peter is a graduate of Dartmouth College.

Amy Hunckler, Managing Director in KPMG Strategy, has nearly 10 years of experience supporting leadership teams at biopharmaceutical, medical device, and diagnostics companies. Amy advises life sciences clients on a wide range of transformation and optimization issues, with particular expertise in market access, product development, and portfolio decision-making. Amy has worked across dozens of therapeutic areas, with a heavy emphasis on core specialty markets including oncology, immunology, neurology, and rare disease. Amy is a graduate of Brown University.

Endnotes

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