



Pathway to success in outcome-based contracting

Navigating payer needs



KPMG Switzerland

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Pathway to success - Implementing outcome-based contracting in the real world

The concept of treatment value has been discussed within the Life Sciences industry for many years. Rising healthcare costs all around the world put pressure on payer's budgets, while quantitative demand and qualitative expectations for medicinal products are rising at the same time.

In this environment, it is no longer sufficient for pharmaceutical companies to demonstrate their product's safety and efficacy data to achieve a high price point eligible for reimbursement. Nowadays, pricing and reimbursement processes inevitably include the assessment of the value brought by the medicinal product.

Based on the idea that prices need to be aligned with the value brought to the healthcare system and the society as a whole, pharmaceutical companies are required to prove that their product's added value justifies the cost.

Although value-based pricing has been identified as a promising solution for some time, its implementation in practice is proceeding along a difficult path.

This whitepaper aims to outline the concept of value-based pricing, where it fits best, and focuses specifically on the based contracts. Here we describe the challenges to its implementation and provide a pathway to success for outcome-based approaches in practice by leveraging on the learnings of real world cases.

From price to value dialogue

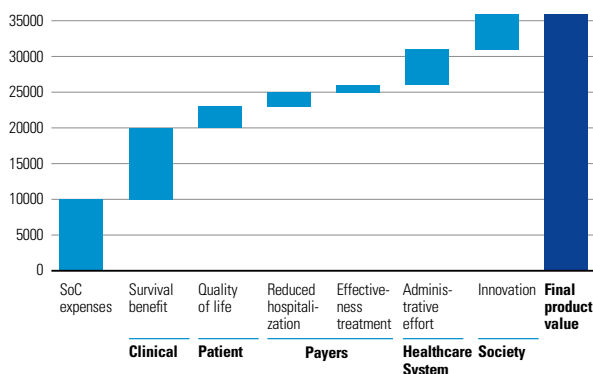
Historically, the marketing authorization was the largest hurdle a new medicine had to pass. Regulatory agencies were set up to assess clinical data and ensure that only safe and efficacious drugs reach public health systems, and pharmaceutical companies used to have near complete freedom in setting the prices. In the current pharmaceutical landscape, with ever-rising healthcare expenditures, budget constraints, and constant public pressure on drug pricing, reimbursement eligibility has become at least an equally high challenge for life science companies.

Payers and Health Technology Assessment (HTA) bodies over the last two decades were moving to apply value-based approaches to price setting, demanding that pharmaceutical companies demonstrate that the therapeutic value is aligned with the drug's reimbursed amount. However, the large variability in methodologies, definitions, and assumptions between geographies, combined with International Reference Pricing system existence, produces a substantial degree of intransparency.

Is value a straightforward metric?

A few challenges come from the very definition of value. Although the two leading approaches commonly used by HTAs in determining value – the Cost Effectiveness and Budget Impact modeling – are relatively well defined, the underlying factors driving the model output vary greatly and provide a lot of room for uncertainties, interpretations, and may result in price negotiation outcomes not satisfactory for pharma, payers, providers, and patients.

Figure 1. Value ladder to determine the price of a theoretical Product



Illustrative, presented metrics are not exhaustive

In theory, the inputs could be determined and quantified: the value added by a novel therapy may consist of the increase in life expectancy, increases in the quality of life, and the reduction of the productivity losses and healthcare costs. The latter may consist of hospitalization event reductions, avoidance of surgical interventions, delayed admissions to nursing homes and/or reduced spend on alternative treatments. Reduction of indirect costs, such as added productivity of the caring family members, may be taken into consideration by some agencies too. Figure 1 illustrates the approach of applying the added value principle to determine the price of a theoretical novel therapy.

However, it may be challenging to assign a definitive monetary value to a number of these factors. Further, various agencies give different weights within their frameworks to medicine's efficacy, the magnitude of benefit, the severity, and the frequency of side effects. Even the factors and outputs with a defined monetary value, such as Incremental Cost-Effectiveness Ratio (ICER) thresholds could vary considerably, even within the same agency. For example, the UK National Institute for Health and Care Excellence (NICE) applies three different cost-effectiveness thresholds depending on the disease severity and frequency.

Considering that every country has separate HTA processes, agencies, and healthcare environments, it is clear that the outcomes will inevitably differ. Considering that many countries employ price weighting with International Reference Pricing strategies, it is not surprising that the negotiations take time, and the average Market Access delay across EU-29 is reported to be 473 days according to the 2018 EFPIA WAIT study.

A substantial degree of uncertainty also comes from the pharmaceutical companies that design clinical trials in order to reach the regulatory approval as fast as possible, inevitably reducing the level of confidence in their medicines' effectiveness outside of the clinical trial setting. Reaching pricing and reimbursement decisions based on the limited data set presents a challenge and, in order to hedge the risks, a variety of Managed Entry Agreements (MEAs) have been introduced and tried over the past decade to allow market access to medicines while sharing the cost of uncertainty between the payer and the pharmaceutical company.

Navigating Managed Entry Agreements

MEAs are contracts that can be used for mitigating the uncertainty regarding a medicine's relative effectiveness, cost-effectiveness, or budget impact. The success of an MEA relies on assigning the right drug to the appropriate deal type, the two main MEA groups being financial-based agreements and outcome-based agreements.

Financial-based agreements are not linked to the health outcome a medicinal product provides to the patients. The most simple (and common) form of such an agreement is a discount, which does not require additional monitoring infrastructure, needs little administrative effort, and allows patient access in a geography. If the discount is kept confidential, the international reference pricing is not (or rather has not been historically) affected for pharmaceutical companies.

The more complex examples include rebates, which involve a separate transaction. Some flexibility may be built into the rebate contract, and the size of the rebate to be repaid can depend on the sales volume. Other

schemes may involve entering into agreements to provide medicines at no cost for a patient population, which would result in an outcome similar to a discount. In yet more complex schemes requiring monitoring infrastructure, payers may impose a cap on the reimbursement amount paid to manufacturers: either in terms of patient-treated, total expenditure per year, or the number of doses per treatment.

One such example is the UK dose capping scheme for Lucentis, a drug used for Age-related Macular Degeneration. Under the arrangement, NICE covers the first 14 injections per treated eye, whereas Novartis pays for any subsequent treatments¹. These schemes already require certain IT and supply chain infrastructure, and are hence not feasible in every geography.

Coverage with evidence development

The uncertainty surrounding the long-term efficacy of innovative drugs with limited data evidence has led to the development of agreements of Coverage with Evidence Development (CED), or conditional reimbursement.

¹ www.nice.org.uk/guidance/ta155/documents/appendix-1-dose-capping-scheme-summary-proposal-to-nice2

Figure 2. Taxonomy of managed entry agreements

OBCs connect reimbursement to the value of a pharmaceutical product and are an avenue to share risk and align incentives.



Representative list – not exhaustive

CED agreements link the coverage decision to the collection of additional data on efficacy, safety, or other disease-relevant metrics. Such agreements are commonly limited in duration, and are eventually switched to regular reimbursement if the collected evidence supports it. However, the one considerable complication of CEDs is that Real-World Data (RWD) is inevitably different and may not be comparable with clinical trial information. Eventually, the collected data may become irrelevant with the naturally changing clinical practice.

Value-based agreements, performance-linked reimbursement, and outcome-based contracting

The payment, however, can be tied to the actual treatment outcome, i.e. the medicine is reimbursed only in the case it is efficacious for a given patient. This represents a direct link to the actual value provided to the patient and the system.

A few names exist for the same concept where the reimbursement is linked to the drug performance. In these agreements the real-world utilization is managed, guaranteeing cost-effectiveness of a new medicinal product or healthcare technology at the individual patient level.

Clearly, the single most important prerequisite for the existence of such a contract is the ability to define and agree on the outcome. The indication treated by the medicine has to have a clear and objective measure of the medicine’s efficacy. Not surprisingly, the field of oncology pioneered the use of outcome-based contracts (OBC) for this reason: disease progression in oncology is well defined, and the definition of the other key metric, survival, does not need a discussion.

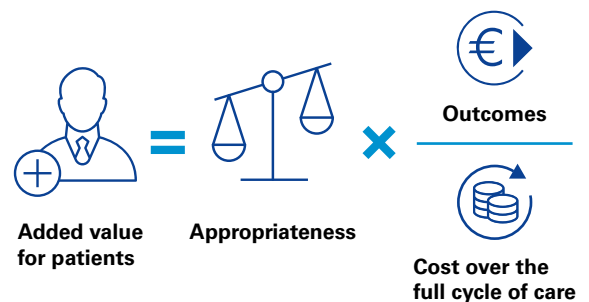
A few setups of the financial terms were proposed for OBCs. A payment to a pharmaceutical company can be triggered after an outcome is confirmed. An outcome and its degree can determine the level of a discount offered to the company, or the level of the rebate paid by the manufacturer to the payer. For very high priced medicines, annuity payment schemes were developed where every next instalment is paid only if efficacy is confirmed for the patient after a period of time.

Where outcome-based contracting fits best

The concept of outcome-based care aims to offer a personalized care that is coordinated, comprehensive, anticipatory, and longitudinal. Outcome-based care is likely to have the highest utility in treatments that promise quantifiable benefits in a defined patient population. Offering a high-priced medication that can be highly efficacious in only a tiny subset of patients may bring an overall medical benefit to society, but is unlikely to be affordable. On the contrary, being able to accurately define the population where the medicine will be efficacious, and ideally curative, may offer cost effectiveness even at very high price points.

The ability to increase the efficacy likelihood, either through the use of biomarkers predicting the therapy efficacy, through the design of targeted therapies, or through the implementation of integrated care pathways that result in a highly increased probability of the beneficial outcome, are all aimed at increasing the “appropriateness” part of the value equation.

Defining value in healthcare

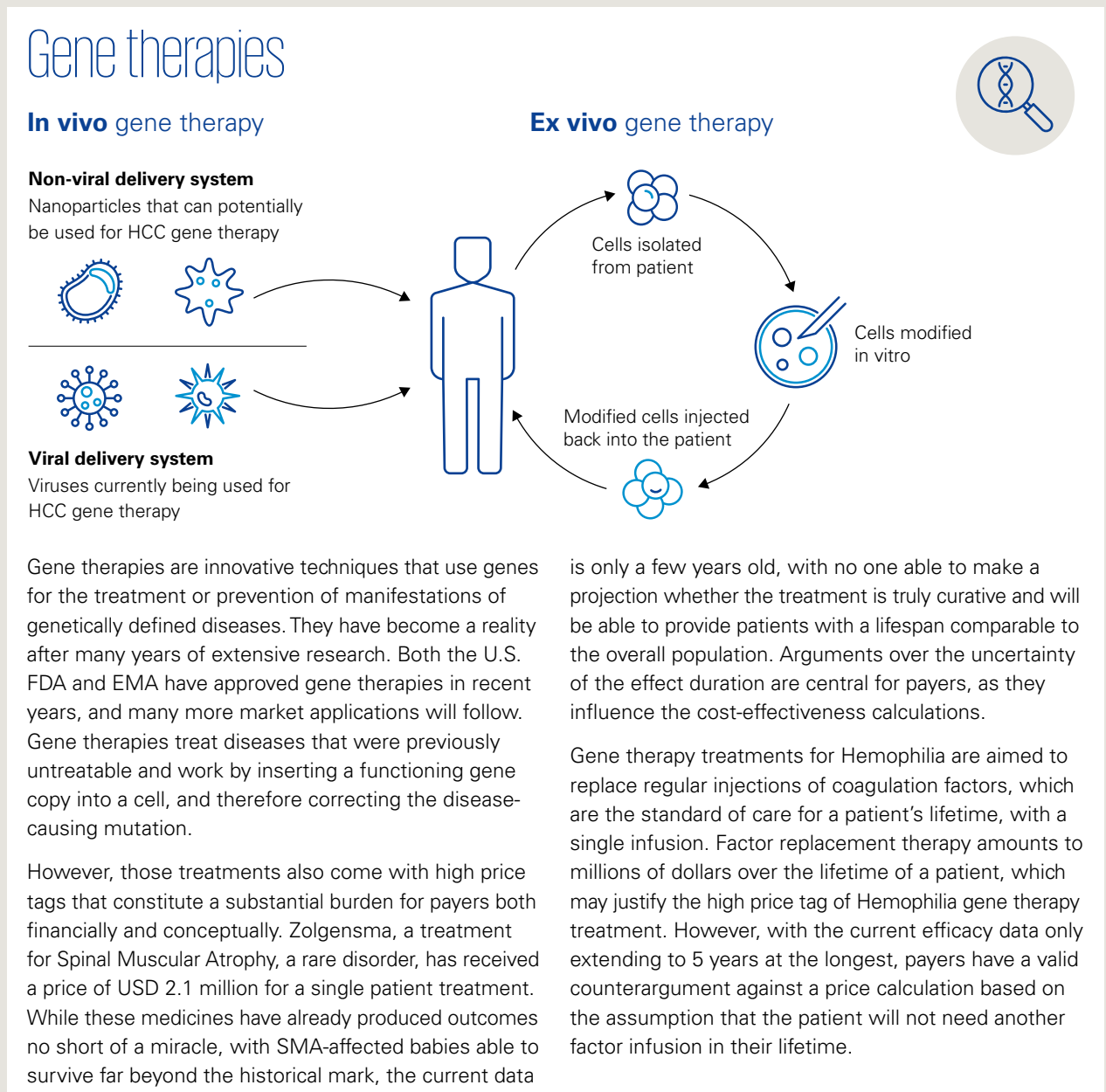


ATMPs, including cell and gene therapies, as the ideal use case for Outcome-Based Contracting

In today’s world, innovative treatments transform lives of many patients. Progress in Advance Therapy Medicinal Products (ATMPs), such as cell and gene therapies, addresses the root cause of the disease and offers a promise of cure, sometimes even after a single product use. In many cases, a lengthy, costly and oftentimes tormenting treatment process for patients is replaced by a single infusion.

The examples include the unprecedented efficacy observed in certain blood cancers with CAR-T cell therapy approaches, which became a reality in the past few years. Gene therapies offer the promise of curing a range of diseases including genetic blindness, Hemophilia and Beta-Thalassemia, replacing frequent visits to physicians and transfusion centers.

While the R&D pipelines in gene and cell therapies are growing, affordability and patient access present a unique set of challenges that includes great uncertainty about the long term benefits, uncertainty over value definition from the perspective of multiple stakeholders, and ultimately, the challenges of affordability and cost perception by payers.





1

The value of a healthcare product is a complicated metric, which among other factors also depends on the healthcare environment of the country – international comparisons of one-price-fits-all approaches are deemed to produce conflicts

2

Uncertainty over efficacy is inherent to therapeutics, managed entry agreements are applied to manage the risks

3

Outcome-Based Contracting (OBC) is aimed at binding commercial outcome to a clinical outcome of a patient – manufacturer receives payment only if the intervention helps the patient

4

OBC implementation supports addressing uncertainties over medicine efficacy, provides faster access to innovative treatments, and increases the efficiency of the funds used

Outcome-based contracts: benefits and challenges

Benefits of outcome-based contracting

As already noted above, pharma should consider entering outcome-based agreements only when the right conditions are met; a clearly definable outcome, and a reasonable certainty of activity in the target patient group. When these two conditions are met, the benefits could be enjoyed by all the stakeholders involved.

Benefits for pharmaceutical companies

The readiness to enter an outcome-based agreement can enable pharmaceutical companies to have market access in geographies and settings that would have otherwise been locked for the product. With gene therapy costs extending well into the 7-digit range, combined with the long-term uncertainty over treatment efficacy, being ready to receive a payment only for the patients in whom the treatment provides a measurable benefit can represent a path to convince payers to provide coverage.

Also, such agreements may enable reimbursement for more established therapeutic modalities to expand the geographic footprint. Targeted kinase inhibitors have become a mainstay of cancer therapy in the Western markets, however they remain out of reach for much of the world as prices for many protected molecules remain unaffordable for broad coverage in many countries. However, in integrated care centers, which are increasingly common in emerging markets, the payers may look for the possibilities to initiate coverage. Such access may provide a basis for starting relationships in the growing markets, and for establishing the presence for future expansion.

In the case where a few products have the same mode of action, and clinical differentiation is uncertain, entering an outcome-based contract can offer a competitive advantage and faster market access.

Further, if the reimbursement is bound to the actual clinical activity of the product, the company may decide to take the risk of providing the product in indications where a reasonable assumption of efficacy exist, but a

formal application to the regulatory authorities has not been accomplished. Such “off-label” use may be increasingly justified in oncology, with the continuing revolution of tumor molecular definition rather through the tissue of origin.

Importantly, entering an outcome-based agreement allows the pharmaceutical company to keep the desired list price for the medicine. As International Reference Pricing remains a reality, the importance of this factor cannot be overstated.

Benefits for the payers

Sharing the risk over medicine’s efficacy with the producer is the key benefit of outcome-based contracts for the payers. With the ever-increasing healthcare costs combined with budget limitations, the ability to maximize the value through outcome-based agreements represents a transparent and implementable path. Paying only for therapies producing clinical results leads to the more efficient use of capital and helps to avoid wastage.

“Outcome-based agreements allow us to achieve the balance between the improvement of patients’ conditions and sustainability. Efficacy and safety for the patients is a prerequisite, but we cannot forget about economic sustainability: going forward we will have to face more and more affordability challenges.”

Payer, Italy

An integral part of OBCs is the collection of patient-level longitudinal data on the efficacy and performance of the treatments. It is hard to understate the potential for learnings and actionable knowledge generation here. Integrating the infrastructure to track the outcomes enables the payers to gain insights into the real-world utilization of medicines and resources way beyond the drug in the scope of a value-based contract. These advanced data can inform future decision-making and resource allocation optimization.

Further, establishing the contemporary infrastructure compliant to data privacy regulations allows payers to shape the future healthcare landscape, and learn how to benefit from the data-driven healthcare today.

In the markets with a developed private payer landscape, being open to outcome-based contracts, and thus being able to provide novel medicines to the insurance plan subscribers, can offer a competitive advantage to a payer. Likewise, OBCs create another lever to stimulate competition between manufacturers, as the outcomes and value provided by their products is more transparent to payers, ultimately resulting in higher negotiation and buying power benefitting patients and society as a whole.

Benefits for providers

Physicians, hospitals and care centers have the mandate of providing the best available care to their patients. Ensuring that novel treatments are available, and doctors are gaining experience with breakthrough therapies is an objective in itself.

Further, novel therapies have the possibility to free up resources elsewhere. In the aforementioned example of Hemophilia gene therapy, removing the need for frequent coagulation factor administration results in freeing the infusion chair capacity, nurse and physician time.

“There is a market for OBC for treatments with high prices, and where the duration of a drug efficacy and severity of side effects are uncertain. Because you do not want to measure every patient as it would be a huge administrative burden. It gets easier with digitalization; however, outcomes have to be clear. There will be an increasing need, but the focus will remain on few areas.”

Sick fund, Germany

The ability to collect real-world data on the drug and resource utilization, as well as on actual therapy and treatment outcomes, is offering an opportunity to providers to optimize their decision making, their resources, and to generate valuable knowledge to share with the clinical community.

Benefits for patients

For patients, the benefit is in obtaining faster access to reimbursed novel therapies. Importantly, this concerns cases of both new product introduction, and the facilitated coverage for off-label indications with reasonable efficacy evidence for launched medicines. If the pathway of sharing the outcome risk with the pharmaceutical company is established through existing outcome-based agreements, the threshold of accepting it for other products will likely be lower at the given payer organization.

Considering the high costs of ATMPs combined with limited data availability complicating standard HTA evaluations, Outcome-Based Contracts may become a real enabler of access to these life-saving interventions.

Industry insights

All of the large pharma companies are committed to moving towards value-based healthcare, and the majority have already commenced driving this transition through a variety of initiatives around the world.

Johnson & Johnson implements – in cooperation with Swiss hospitals – programs for value-based healthcare that are designed to optimize the patient care while reducing the cost. They put special emphasis on

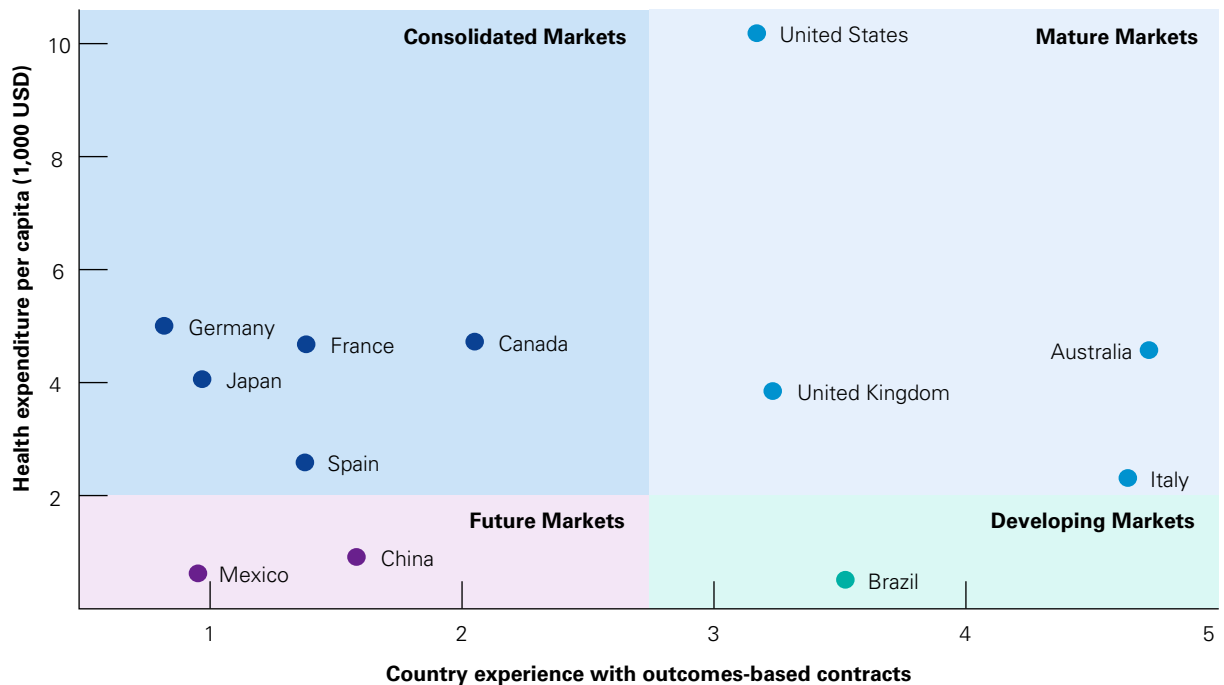
collaboration with various stakeholders and standardized processes.² Novartis' position on value-based pricing focuses on R&D outcomes that are of significance to patients as well as complementing their medicines with value-adding features.³ Likewise Roche's value-based pricing approach concentrates on providing innovative treatments to patients, but also on collaborating with the governments and payers and granting them more autonomy regarding reimbursement decisions.

Country maturity



Country health expenditure per capita and experience with OBCs

Countries with OBC experience could be found across the spectrum of healthcare resource availability



Sources: OECD, Worldbank, Navigant, KPMG Payer primary market research

² www.jnj.ch/geschaeftsfelder/stories/projekte-fuer-ein-bezahlbares-gesundheitswesen.html

³ www.novartis.com/sites/www.novartis.com/files/novartis-position-on-value-based-healthcare.pdf

Challenges to implement OBCs

In the previous chapter we outlined the benefits of Outcome-Based Contracting, as well as the two prerequisites – the ability to clearly determine the care outcomes, and to identify the patient population for which the medicine is likely to produce the desired outcome. These prerequisites trigger a few technical challenges that need to be overcome to secure successful implementation.

Clear and measurable endpoints

The importance of this in the outcome-based contracts cannot be overstated. The outcomes have to be agreed upfront, and all the parties have to ensure that the treating physicians and facilities are able to unambiguously determine the endpoint.

Outcome traceability

The outcomes have to be tracked and communicated from the patient or treater to the payer and the pharmaceutical company. This implies that the necessary data collection and transmission infrastructure has to be in place at the time of the launch. Due to the system and administrative requirements to execute OBCs, we are seeing that 3rd party providers are gaining in importance to support healthcare systems to broaden the application of outcome-based contracts.

Further, the outcomes should be tracked as close to real time as possible, or the data collection intervals, such as physician visit schedule, has to be agreed in the contract. This requires setup of reporting systems allowing it in a manner compliant with local and international data security and privacy standards.

A few challenges remain in the tracking of outcomes in diseases, in which a longer data collection period is required – e.g. disease progression a year after the therapy. Such challenges should be addressed from a few perspectives including strict follow-up requirements, aligned financial terms of the contract, and sometimes automated technological solutions.

“Effort-benefit ratio of the OBC has to be good for payers, it has to be easy. Then, you need to consider if there will be launch of a better product in 2–3 years. What happens to the contract then?”

Payer, Germany

Relevance of collected data

The collected data have to be clearly interpretable. The challenges of free-text interpretation of Electronic Medical Record data should ideally be avoided. The data input systems have to be designed in a way that allows unambiguous input possibility relevant for the reimbursement decision.

Alignment of stakeholder incentives

OBC benefits pharma through allowing faster market access to their medicines, and payers can optimize the use of their financial resources. Providers, however, are continuing to focus on their core duty – treating the patients, and the additional data collection and transmission requirements may appear as a hurdle. All three stakeholders however have the same ultimate interest, achieving better health outcomes for their patients, which is facilitated through the use of innovative medicines. Physicians need to be aware of the necessity to fulfil the data-related efforts, and ideally be interested in it. The possibility to collect RWD and share data for a possible research and publication may represent such a lever for doctors.

The same real-world data collection is an important add-on benefit for hospitals too, who could utilize it for future optimization efforts, and support in pricing negotiations.

Easy to operate systems and appropriate IT infrastructure

The implementation of OBCs requires a certain level and architecture of the IT infrastructure. Insufficient digitalization, insufficient data quality, and data silos, are all common issues contributing to slower than wished adoption of outcome-based contracting. These hurdles need to be overcome, and new IT solutions leading to infrastructure changes sometimes need to be implemented.

When implementing such systems, the efforts to report, transmit, and analyze the data have to be made as easy as possible for providers and payers: the use of existing, familiar systems has to be maximized. If a separate software has to be used for a given agreement, it must be as simple and user-friendly as possible, and ideally offer additional clear benefits to the operator. In any case, the burden has to be minimal.

Reasonable and clear financial terms

The objective of every outcome-based agreement is to share the risk and outcome uncertainty between the manufacturer and the payer. The terms must reflect this, and a reasonable justification, including estimates of risk quantification, has to be provided to all parties. The manufacturing company may carry a considerable part of the risk. Gene therapies are commonly highly customized, high technology treatments with costs of goods commonly in the range of hundreds of thousand dollars per treatment. Annuity models spreading the revenue payments over years with cost incurred at the treatment date requires separate planning.

Pricing of the contract

The ability to price the OBC to the agreement of both parties is a challenge as formidable and critical as the ability to agree on the care outcome. This factor deserves a few whitepapers in itself, and here we touch it only tangentially. Pharma and payers alike need transparent and solid methodologies and tools to quantify the risks and value for both sides. Institutions such as ICER are continuously working to develop solutions to solve this issue.

Agreement between parties

Both payers and pharma have to see the contract as the solution to reach their own goals. Transparency in data, methodology, and challenges of each party should be clearly communicated, and ways to find a middle ground should be pursued by each party. Transparency is an important factor to stimulate trust and understanding between the stakeholders. Disagreements over outcome measures, incentive mechanisms, and financial terms were identified among the leading reasons for breakups of negotiations for OBC agreement in a recent study⁴.

Deal breakers must be identified early on and addressed accordingly. As such, Medicaid Best Price Requirement is often cited as a barrier to OBC implementation in the US. The extent of this effect needs to be assessed early on for the specific therapy, ways to address it should be identified, and dialogue with relevant stakeholders should be established. CMS guidance targeted at fixing is in development.



1

An outcome needs to be clearly defined and agreeable for all parties

2

An outcome needs to be traceable, systems must be in place

3

Payers and manufacturers need to be able to agree on the pricing

4

Incentives of an OBC have to be aligned for all the stakeholders – manufacturers, payers, providers, and patients

Pathway to success in value-based pricing

A digital-focused implementation approach

The roadmap to success in setting up outcome-based agreement encompasses five phases allowing companies to examine a series of strategic options that can help them achieve a competitive advantage⁵:

I. Validate and agree on the framework

In the first step, the appropriateness of an outcome-based contract for the product and specific market needs to be assessed, and internal stakeholders across organizational functions need to get on board.

An outcome-based framework is a solution to achieve market access in a market where broad coverage cannot be reached. The first step is to ensure that OBC is an appropriate solution. Are the endpoints

well defined? Can they be accepted by payers? Are physicians able to collect the data? Does the necessary infrastructure exist in the country, or could it be implemented with a reasonable investment?

Secondly, internal pharma company organization has to be aligned behind the decision to engage in the agreement. What implications does the OBC have on the functions? Finance, regulatory, legal, supply chain, quality, pharmacovigilance: stakeholders across the organization need to build capabilities, necessary capacity, get onboarded, and be able to provide feedback and commitment. Based on insight across the organization, the checklists will be finalized to identify existing gaps, and ensure a comprehensible framework is built.

Outcome-based agreements approach

1 Outcome-based framework	2 Market assessment	3 Technical design	4 Contract negotiation	5 Roll-out and maintenance
Stage objectives				
Assess appropriateness of outcome-based contracting for the product and market in scope	Determine healthcare system readiness for and experience in outcome-based contracting	Determine technical enablers for successful OBC implementation and roll-out	Manage payer outreach with predefined commercial and technology strategy	Roll-out the OBC in new jurisdictions, secure implementation, and monitor outcomes
Stage outputs				
Key OBC implementation and tracking assessment criteria for product and country	Product and market readiness reports validated with local stakeholders by therapy area Shortlist of recommendations to move to technical design	Approved solution concept and technical design blueprint Technical implementation roadmap and charter	Pricing algorithm design, contract negotiation strategy Pilot rollout plans in selected geographies	Integrated technology-supported outcomes-based contract Business continuity with continuous monitoring and improvement

⁵ Value-based pricing: sub-proposition, KPMG 2017



Girisha Fernando, CEO of Lyfegen, a health technology company providing digital platforms aimed at enabling outcome-based contracting, has shared his views on OBC in an interview:

What are the key success factors to execute outcome-based contracts for payers and manufacturers?

It is crucial for all stakeholders to understand why value-based contracting is applied by clearly defining the goals and objectives value-based contracting is to achieve. That is why we collaborate with KPMG to help stakeholders define strategies and translate these into successful value-based contracts with tangible benefits. Lyfegen firmly believes in empowering payers and manufacturers with knowledge and experience and equipping them with technical capabilities. Lastly, but clearly the most important success factor, is to focus from the very beginning on the benefits value-based contracting can create for the patients.

How can technology enable OBC?

Successful value-based contracting requires transparency, compliance, efficiency and trust from all involved stakeholders. Data, sometimes sitting across various silos, is a critical factor and thus at the foundation of such contracts. In the past, we have seen stakeholders that face these challenges discouraged from entering and executing value-based contracts because the costs negate the benefits. Today, stakeholders can make use of innovative technology platforms, such as the platforms provided by Lyfegen.

We focus on removing technical barriers and inefficiencies whilst enabling transparency and efficiency, allowing stakeholders to move away from resource intensive administrative activities to fully focus on what truly matters – providing better health outcomes for patients.

How will OBC look in 5–10 years?

We at Lyfegen strongly believe that every high-cost drug in the future will be paid for based on the benefit it provides for the patient and healthcare system, using real-world data. This new era has already started, as we are seeing health systems shifting away from fee-for-service and volume-driven approaches to value-based healthcare and thus rewarding providers and manufacturers for good quality healthcare and improved health outcomes. Especially for payers, now is the time to shape the future of value-based contracting. In a sense, the future is now.

II. Conduct market assessment and review available agreement options

Healthcare landscape is different in every country, and stakeholders have different needs. It is crucial to understand who are the stakeholders in the geography, what are their requirements, capabilities, needs, and limitations. Before developing contract options, it is a must to understand the current views and readiness to outcome-based agreements. Entering early discussions with local payers, providers and KOLs to understand feasibility are a critical component of this step.

At this stage different agreement types and possible negotiation levers should be identified. What can the financial component look like – a discount, a rebate, an annuity? What will the possible ranges of acceptable price points be? How often could the outcomes be tracked? How could outcomes be translated into financial terms? What data is available and how could it be used? What could the data requirements be and what could be offered?

III. Identify best practices and the suitable technical solution

Once the available options are identified in step II, they need to be carefully assessed, prioritized, and the implementation path has to be clarified. The technical enablers have to be selected or designed at this stage. It is possible that a few IT solutions may be implementable in the indication and region, and a careful assessment of the appropriateness, ability to integrate payer, provider, and manufacturer data, as well as to secure data privacy and security has to be performed. The suitability for RWD collection and capabilities in automation, analytics and visualization should be integrated into the assessment too, but the operational simplicity and functionality should be considered paramount.

The contract itself could be designed now, and based on the understanding of stakeholder needs, a negotiation strategy has to be finalized.

IV. Negotiate the contract and pilot roll out

Once the negotiation strategy is clarified, the definitive reach out to the payers can be initiated. Importantly, the approach has to be integrated, and include the IT enablers lined up at the start of the discussion.

The organization may decide to initiate the rollout at pilot sites, which could also be acceptable for payers not experienced in outcome-based contracts. The work has to start with identifying and prioritizing possible pilot sites, which should be capable of implementing the contract and data requirements, and having sufficient volume of addressable patients for data and experience generation.

It may be necessary to close agreements in sub-geographies or with single payer organizations even in countries with universal coverage. Such, advanced therapy agreements currently may need to be set separately with individual sick funds in Germany. Having the first agreement closed and implemented could represent a very significant signal to other stakeholders within the country and internationally.

V. Final roll out, expansion, and continuous improvement

Expansion to the national level may prove to be a long journey of single steps. Given the tremendous complexity of the current healthcare systems, and the responsibility over patient lives and country budgets, planning each of the steps is paramount. Planning informed by extensive discussions with local stakeholders and supported by modern IT capabilities builds a solid path forward to individualized healthcare with maximal value.

Adapting to thrive: key success factors

While healthcare systems transition towards a radically different reality, ripples of impact will be felt by stakeholders across the health ecosystem. Of particular relevance are Life Sciences companies, for whom these changes will entail profound effects. To most optimally navigate the waves of change, Life Sciences companies will need to fundamentally reassess their traditional approaches and turn challenges into opportunities. Through their actions, companies will need to position themselves as trusted partners delivering superior value and outcomes.

I. Know your customers

Understanding the stakeholders, their needs and limits is paramount to establishing the ground and negotiation strategy for a successful outcome-based agreement. Incentives for each stakeholder group need to be integrated into the OBC design to secure wide product adoption. Understanding the current infrastructure and processing capabilities, and how to complement them will influence the choice of the supporting solution and will be an integral part of the agreement. Payers are only one part of the ecosystem. If physicians and hospitals will not be able or willing to utilize the system, the access to the medicine will de facto not be achieved, even if a reimbursement agreement is reached. Finally, the ultimate customer is the patient, and keeping in mind their needs while designing the contract will contribute to the success and adoption of the product.

II. Take a more commercially-aligned approach to delivering outcomes

Since improving health outcomes lies at the very core of evidence based healthcare, in the future Life Sciences companies will be fully judged based on the outcomes they are able to deliver. Thus, to thrive in the new reality, players will need to focus all of their efforts on continuously delivering superior patient outcomes. Not only will they need to incorporate patient inputs into clinical trial design, but also to reorganize and redesign their entire commercial access strategies around value and outcomes delivery. In this sense, outcome-based commercial contracting models have been gaining increasing attention during the past years and a number of companies are already experimenting with them.

III. Plan activities and engage stakeholders early

Understanding the needs and capability limitations of parties may be necessary early on – at the design of pivotal trial endpoints at the latest. Options for the contract design, software, hardware and legal requirements have to be planned well ahead.

If annuity payments are a likely possibility, the financial aspect has to be carefully evaluated, as implications for accounting, tax and working capital could be considerable for both pharmaceutical companies and payers, and advanced planning is required, especially for small companies that cannot cushion working capital with revenues from other products.

“You need to overcome payer concerns: they will have to reimburse the same drug for some patients, but not for others. You need to make clear when the treatment is a success, and when it is not. You need to overcome the issue of additional administrative burden as it requires human resources, which are not free. So finally, you need to demonstrate that for the same result, it will not cost more.”

Payer, France

Patient advocacy groups could prove to be important players in the design and negotiation of access agreement. Early engagement with them to understand the needs and communication channels may be fruitful.

IV. Adopt a patient-centric corporate culture

Proving superior outcomes should be based on patient insights. Thus, truly outcomes-focused Life Sciences companies will increasingly move towards a patient-centric corporate culture that permeates across the entire organization and enables patient voices to be heard. Listening to the patient should be done across the entire value chain, from identifying patients' unmet needs during drug discovery and clinical trials to measuring health improvements during the commercialization phase. Placing the patient at the heart of everything they do might entail a number of changes for Life Sciences companies, depending on how advanced they are in patient centricity. Some of the internal changes to be considered include policies, governance structures, internal processes, as well as employee education and reward schemes that will create a favorable company-wide environment for listening to the patient.

V. Provide beyond-the-pill solutions

Recognizing that the future healthcare model will be patient centric and coordinated, Life Sciences companies must increasingly provide an integrated offering across the patient pathway that delivers outcomes and value.

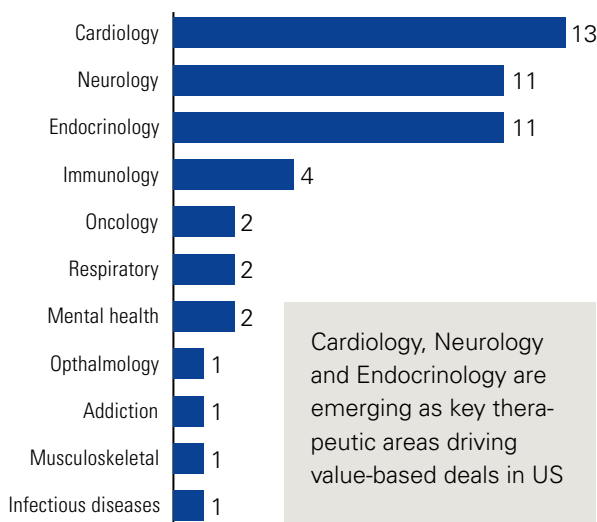
This integrated offering will blend drugs with further patient services to deliver better health outcomes and an enhanced patient experience. Providing such extra services or beyond-the-pill solutions will move from being a differentiator and source of competitive advantage to being a prerequisite for companies to be taken seriously.

VI. Focus on the right settings first

The threshold to accept the implementation of the first Outcome-Based Agreement in a geography may be high. While we are strong believers that OBCs will at some point become reality also for large indications, focusing first on ATMPs, rare diseases, high-price indications with clearly definable validated and trackable outcome measures may be the right place to start, where the payer and provider readiness is mature. Pilot approaches may turn out to be a viable option to enter the space, with small patient cohorts, or few integrated healthcare centers.

While Europe led the way in designing first OBCs, the US is catching up, and remarkably readily in larger indications (see Figure 3), where the contract with payer represents a competitive access advantage. If agreements for PCSK-9 monoclonal antibody therapies (Praluent and Repatha) still fall under the category of medicines considered expensive, the agreements closed for Victoza and Jardiance for the management of diabetes are clearly opening the path for the new

Figure 3. Outcome-Based Deals by therapeutic Area in the US, 2016–2019



generation of outcome-based agreements in markets with high prevalence. In the agreement closed between UPMC and Boehringer for Jardiance in 2018, the reimbursement for the drug is dependent on the overall cost of care for the treated diabetes patients. This represents a bold and future-oriented agreement where the use of an intervention is aimed to reduce the cost of care for the patients in an indication.

VII. Publish the VBAs

Publishing the agreements could provide a range of benefits beyond transparency: it could signal the readiness of the infrastructure and thought leadership to implement the solutions, it could trigger competitive dynamic, and promote implementation of future agreements for follow-up products.

VIII. Embrace digital and data-driven strategies

Evidence-Based Healthcare relies on data to measure and prove the value of biopharma’s products. In the future data will be present across all stages of the pharma value chain: from drug discovery and clinical trial recruitment to sales and delivering an effective customer experience, utilizing data in the right way is key. Most pharma companies have already started to build some digital capabilities.

Such initiatives to integrate data analysis and digital into the business model are increasing, but to successfully ride the wave of healthcare transformation, biopharma will need to fully embrace digitization as a core element of their business models. Real-time data collection during a drug trial can show early signs of risks so that safety or operational problems can be removed before they get too big. In marketing and sales, analysis of the sales cycle leads to a more targeted and tailored approach to providers and patients, identifying who is most likely to utilize the product and comparing different methods. Patient follow-up can be taken apart and investigated too, through the analysis of data collected by a patient’s wearable devices. All these approaches will allow biopharma to adjust its offering and improve customer experience. But while there are multiple ways in which Life Sciences companies can start to embrace digital, they will need to adopt a comprehensive and holistic data-driven strategy to improve outcomes and make a difference.

Digital-enabled OBC use cases

The application of digital enablers have allowed payers to implement OBC agreements in complex settings, where other access and reimbursement solutions were not possible. We have collected three real world OBC cases conducted together with Lyfegen.

For a novel oncology therapy

For an additional oncology therapy indication

For a medical device

Customer situation



A large pharmaceutical company and a private payer seek to make an innovative cancer therapy accessible to patients in Latin America

A large pharmaceutical company and a national decision maker in Europe seek to offer more indications for a cancer therapy

A large Med-tech company seeking to move from selling devices to selling outcomes in Europe

Project rationale



No commercial agreement could be reached between the Pharma company and private and public healthcare payers due to heavy budget constraints and uncertainty of the performance of the therapy, leaving patients unable to access the therapy

The private healthcare payer refused to accept a volume-based price as well as a simple discount model for the cancer therapy

Pharma and a European payer could not agree on reimbursement for an oncology drug in a new indication due to uncertainty of efficacy

The price of the therapy for other indications could not be compromised

As a result, a patient-centric, indication-specific outcome-based contracting approach was welcomed by the national decision maker, private health insurers and the pharmaceutical company

Our customer sought to strengthen its market position in Europe by offering its device with a holistic service offering including an outcome-based contracting approach to move from selling devices to selling outcomes

The approach was welcomed by healthcare payers and providers, who are interested in gaining first experiences with this new outcome-based model

Digital solution help



Implement a digital contracting solution, which continuously captures and evaluates patient-level eligibility metrics, outcomes and resulting prices based on the clinical trial protocol of the cancer therapy, and the set price

Implement a patient management system, allowing healthcare professionals to digitally manage their patients

Implement software in connection with a claims database to validate the defined outcomes and calculate financial results. The use of claims data allows for a scalable approach to administer the cancer therapy to patients across the country without the need to connect to disparate hospital data sources.

Implement the solution with an external data source allowing the MedTech company and hospitals to enter bilateral outcome-based agreements by using pre-aligned templates for an efficient setup and easy execution including transparency on and auditability of results

Customer benefits



Patients have access to innovative therapies through a sustainable model for all stakeholders

Patient level reimbursement based on clinical trial protocol with transparency on therapy performance and financial obligations for the contracting parties. A Patient Management tool for Oncologists to support the patients' therapies

Near-real time oversight of patient outcomes, insights to financial exposure, information on real-world therapy application data and experience with this pricing model for future Advanced Therapy Medicinal Products,

Ability to realize, execute and scale value-based agreements across disease areas, devices and partners

Exploring new business models for Medtech and Hospitals with harmonized and digitalized outcome-based contracts

Conclusion

Healthcare systems across the world have been on an unsustainable path for too long. More recently, rising healthcare costs and stagnant quality levels, coupled with disruptive changes in the external environment have created ideal conditions for transformation. At this point, there is no doubt that the future holds a radically different healthcare reality at the heart of which lie actual improvements in patient outcomes and benefits to the healthcare systems as a whole. In this new reality, care will be funded based on the value provided and improvements observed in continuous monitoring of patient health. Such patient-centered care, delivered where the patient is and integrated across the entire healthcare continuum. Providers will be subject to a standard of care that will increase consistency, however treatments will be personalized to the specific background of each patient. Disease prevention, through lifestyle or medicines, will become ever more important.

All of these changes will trigger a number of course adjustments for all industry stakeholders. For Life Sciences companies, these changes will be particularly relevant. To navigate the wave of transformation and come out as a winner on the other side, companies will need to build patient-centric organizations that embrace data-driven solutions and provide beyond-the-pill services to deliver value. They will also have to realign their commercial strategies to incorporate health outcomes into any contracting models. Patient outcomes will be the measure of success in evidence-based healthcare. Thus, by improving outcomes, not only will Life Sciences companies thrive in the new ecosystem, but they will contribute towards a more sustainable healthcare environment that will benefit everyone.



1

Modern technology solutions enable successful implementation of OBCs

2

Planning the activities, understanding the needs of all stakeholders, and creating a roadmap to the design of a transparent contract is paramount to successful implementation

3

Providers, payers, and manufacturers, are ready to embrace OBC as the future of healthcare, and successful cases of enabling patient access to transformative innovative treatments are multiplying



About KPMG's Global Strategy Group

KPMG's Global Strategy Group works with private, public and not-for-profit organizations to develop and implement strategy from 'Innovation to Results' helping clients achieve their goals and objectives. KPMG Global Strategy professionals develop insights and ideas to address organizational challenges such as growth, operating strategy, cost, deals, digital strategy and transformation.

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outcome-based contracting**
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