July 2017

From discussion to implementation: How to negotiate and implement a risk-sharing agreement

At the table with payers and manufacturers

Background

The groundswell of interest in value-based drug pricing models has forced manufacturers to focus on finding ways to measure the value of a therapy. Outcomes-based, risk-sharing agreements are an option for manufacturers seeking to mitigate additional price regulation and access restrictions proposed by payers, politicians, and other stakeholders.

When it comes to implementation, nearly all stakeholders continue to be somewhat skeptical of outcomes-based contracts (OBCs). Complex contract terms and resource constraints continue to be obstacles. Consultants with Charles River Associates (CRA) solicited ideas and opinions of payers and drug manufacturers through separate live discussions to gain a deeper understanding of how to overcome roadblocks to OBCs. Four core themes emerged:

- Greater trust needs to be fostered between payers and manufactures;
- The ability to monitor relevant endpoints and metrics matter;
- Negotiating OBCs is time consuming and resource intensive; and
- These agreements make the most sense when the therapeutic area is changing or not well understood.

In this article, we share the ideas we heard, examine the obstacles, and provide examples of how payers and manufacturers can collaborate to share risk and improve patient outcomes.

Are outcomes-based contracts the flavor of the month? Establishing trust through transparency

Payers suggested that manufacturers' account representatives often come across as disingenuous when presenting OBCs:

"Account representatives appear to feel pressured to present these types of contracts as more of a 'check-the-box' exercise, just because it is 'the new hot topic'."

"Often times it seems like the account managers are bringing forward something that the corporate office came up with just to push this idea."

Transparency and trust are the foundation of a successful OBC. When both parties openly share detailed goals for an agreement and act accordingly, coming to a win-win compromise becomes more of a team effort, limiting the potential for "gamesmanship."

Even when payers believe manufacturers are genuinely interested in an OBC, payers note a reluctance in sharing the risk.

"We get the sense that there is a lot of talk from pharma companies, but when we get to the details and want to finalize these contracts, they see themselves as assuming too much of the risk which may cause them to lose money, so they start adding excessive details to the terms, which make the payer back away."

Manufacturers acknowledge these concerns, and are wary of being outmaneuvered by insurers they view as better equipped to understand and manage risk. "*Payers are not interested in sharing risk, only shifting it to manufacturers."*

Contract negotiations with clear objectives, targeted for specific product and customer circumstances, are essential as is the reality that both parties have to be open to compromise. If contract goals are non-specific and/or avoiding any potential for downside risk, initial conversations may be cut short, or impasses may arise later on, wasting time and resources.

Not all categories are created equal. Measurable metrics and impactful endpoints

Once payers and manufacturers understand each other's goals, negotiating contract terms can still bring challenges. The metrics used to assess patient endpoints should not be so onerous that the cost to collect data outweighs the upside of a contract. Agreement on relevant, measurable, and impactful metrics is essential to a successful OBC and some categories present larger challenges due to the difficulty in determining objective metrics.

Payers suggested that a productive way to develop OBC metrics is to look at primary outcomes in pivotal studies. Some payers agreed that secondary outcomes and other Phase III studies limit a manufacturer's ability to prove its case. Studies provide pre-approved metrics that are easily referenced using clinical trial information, which can save time during negotiations. However, manufacturers were troubled by the potential performance gap in real-world outcomes versus the clinical-trial setting.

One payer told a cautionary tale of using inappropriate hemoglobin A1C thresholds as an endpoint for an OBC in the diabetes area.

"Achieving a 0.3 - 0.5 reduction in a patient with an A1C of 11 is not meaningful; in fact, it becomes gamesmanship on behalf of the manufacturer because they know that any change will be significant for someone who is that ill."

For this reason, it is recommended that the clinical trials data included in the label be used as a starting point for defining OBC metrics.

After ensuring that the patient population and the endpoints are relevant and not skewed, both parties should determine how much time and resources are required to collect data to measure outcomes to administer a contract. For payers, detailed contract terms that require in-depth investigation (e.g. chart reviews) are often not feasible due to resource constraints. Payers prefer straightforward metrics such as lab testing, readmission reduction, and mortality rates. The ability to measure patient outcomes within a year would help ensure that OBCs last no longer than two to three years.

Diseases with clear endpoints like oncology or diabetes, were viewed as the best candidates for outcomes-based contracts. When both parties better understand the product profiles and value propositions of various therapies in a disease class, relevant metrics for contracts within the category can be determined. The parties to the contract can then identify impactful and easily measurable endpoints, in addition to the incremental value of medical costs offsets.

For example, a payer noted that *"a number of new therapies for diabetes may have a higher probability of getting a larger segment of the population to a healthy hemoglobin A1C level that is easy to measure."*

Another payer asked, *"For drugs with many different indications, should a contract be for a drug or specific indication?"* Focusing on an indication can provide clear targets which are well suited for an OBC, making it easier for payers and manufacturers to agree on endpoints and negotiate contracts faster. However, if the disease has too small of a patient population, it may not have as significant an impact on the healthcare plan budget.

A roadmap for simplifying OBC negotiations: start with a standardized approach and process

Both payers and drug manufacturers we spoke with agreed that starting with a template or a memorandum of understanding (MOU) which would serve as a starting point for contract discussions would help initiate a dialogue.

"If the back-end details can be standardized across various contracts, we wouldn't have to recreate different organizational infrastructure for each agreement. This would shorten the timeline, because people would be used to a standard approach and wouldn't have to renegotiate each time, moving agreements past this phase much faster." (Payer comment)

An ideal template would list relevant outcomes and endpoints, omit the specific values, and allow the two organizations to determine the level of interest and broad contract terms. Clearly stating why a certain metric is chosen would provide transparency for current and future negotiations. The body of a template should include a framework of the metrics and time period required to demonstrate the outcomes at issue. It would help if the parties established a straightforward approach to collecting the data that would be required to negotiate and to implement the contract. The majority of payers feel that manufacturers should pay for data collection, as one payer representative noted, *"The data analysis portion of these contracts is so time consuming and costly; manufacturers should pay for it, since in the end, it is benefitting them in a more direct way."*

An efficient negotiation process is a key first step toward effectively beginning an OBC partnership. Payers and manufacturers agreed that a six to eight week timeline for negotiations is

ideal, with six months as the maximum. Where possible payers were hopeful that the standardization would not stop at the initial negotiation.

Payers and drug manufacturers can benefit from communicating the most efficient process and team to manage OBCs once they are in place. For example, the parties should discuss and agree on who may be involved in managing a contract (e.g. contracting specialist, quality representative, medical director, etc.). By developing a basic framework simple enough to work for multiple contracts, but specific enough for one partnership, each party can leverage this structure going forward and save time on future OBCs.

Issues such as the payment structure and monitoring approach are also critical to the ongoing relationship between the payer and manufacturer. Clarity around who will be paid and how, and monitoring contract terms throughout the life of the agreement, aligns both parties to the process.

The appropriate time and a place for an outcomes-based contract

New data, a new competitor, a change in standard of care, a desire for better access or positioning, are all driving factors for outcomes-based contracts. While the impetus for an OBC is often a competitive threat or market change, OBCs can be used for a number of different reasons: to gain market share for new products or to obtain a deeper understanding of how the therapy works in a natural setting, outside of highly controlled clinical trials. The patient outcomes collected throughout the course of a contract can also be used to help determine a product's future access and reimbursement rate.

Outcomes-based agreements can also be used in place of head-to-head studies, for example, when a new therapy is launched or if a previous clinical trial was conducted against a placebo. An OBC can provide real world patient data versus a competitor, and is less expensive than conducting additional patient studies. One payer stated *"Clinical trials are designed to determine the difference of one product versus placebo, not to uncover value or return on investment."*

OBCs may also be used as leverage against legacy contracts, particularly where clinicians question the value of certain therapies, such as biosimilars. A payer noted *"If a product never gets any market use because of legacy contracts, how will a manufacturer ever get to demonstrate the value of the product?"* OBCs can be a means to overcome existing contracts and create opportunities for novel and less used therapies to change the standard of care.

It is critical to periodically assess contract terms, how data are collected, and the ongoing relationship among parties. For example, a quarterly review of how a contract is being maintained may uncover inefficiencies or miscommunications before it is too late to make adjustments to behaviors or terms.

Both payers and manufacturers mentioned that it is not always necessary to renew an agreement. "*Once you go through an OBC, both parties know what patients are the best candidates and what the response rate will be; it may not make sense to continue the agreement because you are selecting patients who are going to be the best responders and you will have fewer failures."*

At this point, both parties can save time and resources by ending the contract and adjusting the rebate or access to the therapy, if appropriate.

Lastly, for manufacturers, a major concern is how to operationalize government reporting such as Average Selling Price (ASP), Medicare Best Price. *"There's no clear legal guidance or operational processes for certain types of risk sharing deals,"* one manufacturer noted.

So what will it take to "sign here"?

From the payers' perspective, manufacturers need to put forth genuine contract proposals and be prepared to take on risk if they want to prove the value of a therapy. Payers also felt strongly that manufacturers should cover the cost to collect data, since in their view, OBCs will benefit manufacturers through improved access.

From the manufacturer's perspective, to move these conversations further along, standardized frameworks for agreements can be created to define negotiation and data collection processes. Contract terms need to be relevant to clinical trials and recent studies, easy to measure on a regular basis, and, ideally, reduce costs for healthcare plans.

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*The authors would like to acknowledge the contributions of **Robert Navarro** and **Brooke Bonet** to this article.*

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