CATALYST IMPLEMENTATION BRIEF

Is an innovative contract right for you?

Innovative contracts can offer significant benefits for stakeholders delivering novel drugs and medical products to patients — but they require resources to design and implement. This Implementation Brief outlines key considerations that payers and developers may assess when considering innovative contracts as compared to traditional discount-based contracts, and provides a checklist of assessment steps.

What's covered

The potential value of an innovative contract typically stems from mitigating the risks associated with the use of the medical treatment under consideration. If the treatment is new or innovative, it may pose risks and uncertainties: uncertainty for payers regarding the number of patients likely to be treated and the real-world performance of the treatment, and uncertainty for developers with regards to facilitating access to their product for appropriate patients without unnecessary barriers.

Innovative contracts can address different areas of uncertainty and risk. However, these contracts may require more or different resources to implement; thus, payers and developers must evaluate whether the potential benefits of an innovative contract outweigh the resource cost that would be needed for implementation. The impact of other considerations including contract requirements around utilization management and site of care must also be considered. Other stakeholders, such as employers and third-party service providers, may also be involved in these contracts.

The considerations in this brief are described from a payer's perspective, with additional notes about issues specific to developers.

CLINICAL PERFORMANCE ASSESSMENT

For payers, a key area of risk with a novel or innovative treatment is posed by the inability to accurately predict how well a product will work for a given patient or group of patients. Clinical trial data is a key source for payers to assess the treatment's potential outcomes and significant side effects, including both short- and long-term performance. Payers will also assess expectations of how real-world treatment performance compares to clinical trial data.

To address real-world performance risk, developers may offer an innovative contract that provides a rebate for less than anticipated performance or a traditional contract with discounts. For example, if a developer offers a 30% discount, a traditional contract may be more appropriate for a payer's needs and eliminate the additional tracking requirements that would accompany an innovative contract.

While new and innovative treatments pose uncertainty, they can also lead to potential cost offsets in the long-term. For example, if a patient is cured of beta thalassemia, they no longer need other drugs for that disease, leading to long-term savings. Assessment of these potential long-term outcomes and cost off-sets should be part of the overall financial impact of the product.

In considering a potential innovative contract, payers and developers must assess what outcome metrics are feasible to collect and measure to accurately reflect the treatment's clinical performance.

Utilization management parameters may also be part of the contract; these parameters may impact the anticipated number of people likely to be treated. A comparison of the potential impact under each contracting scenario, innovative contract to a traditional contract or no contract, will be required.

BUDGET IMPACT ASSESSMENT

Budget impact is a function of the number of patients treated and the expected payer cost net of discounts, off-set by reduction or elimination of other treatments. Ultimately, payers will need to assess the budget impact of various contracting strategies—traditional and innovative—on utilization and cost for a given plan year.

The budget impact includes **actuarial risk**, or predicting how many patients a given health plan will have on the therapy. To assess potential patient

numbers, payers may evaluate the prevalence and incidence of the treated disease in their population. They should assess the unmet need for patients with the disease, as well as their current treatment options and alternatives.

Developers can also undertake a similar evaluation of the impact of the treatment by business segment. For both stakeholders, Paying for Cures Toolkit includes tools that can assist in this assessment.

In addition to patient prevalence and incidence, it's important to assess the patient and provider demand for the treatment to determine how many people are likely to utilize it. Payers should ask: how likely is the treatment to be used in my population –- and how likely is it that eligible patients decline treatment? In some cases, there may be other treatments available or in the pipeline that could be more successful or require less invasive procedures, making them more attractive to patients.

Greater patient volumes and/or more variability in treatment outcomes may prompt developers to explore an innovative contract to improve access, leveraging the predictability associated with larger populations. Meanwhile, lower patient numbers may lead to small payer considerations of an innovative contract to address the uncertainty of budget impact relative to the number of patients that might be treated, particularly with a high-cost treatment.

With some therapies, additional risk may be posed by situations in which payers reimburse for a one-time therapy upfront, then its benefits accrue over time, generally outside of the budget cycle of interest. This situation, known as **payment timing risk**, primarily applies to cell and gene therapies (CGT).

Payment timing risk may also refer to cash flow demands when a new treatment enters the market and many patients are eligible. This can result in a very large impact in early budget cycles and result in payer reluctance to provide full access to the product.

A comprehensive assessment of budget impact will also incorporate an assessment of tools payers may already have tools in place to address high-cost cases, such as stop loss and reinsurance.

The Value Based Contract Impact Assessment Model (VBCAM) is one resource that may aid in assessing different traditional and innovative contract options. See the VBCAM use case study document for more information about how to use this tool.

OTHER CONSIDERATIONS

In addition to the clinical and financial assessments of a therapy, organizations should consider legal and regulatory implications of innovative contracts and the contract's potential impact on other stakeholders. They may consult legal counsel as well as providers and patient groups.

CHECKLIST FOR ASSESSING THE POTENTIAL VALUE OF AN INNOVATIVE CONTRACT

- ☐ Study the clinical performance of the product to assess potential patient outcomes and significant side effects.
- ☐ Consider potential short-term and long-term performance of the product.
- ☐ Evaluate the prevalence and incidence of the treated disease in your population.
- ☐ Assess the unmet need for patients with this disease, as well as their current treatment options and alternatives.
- ☐ Identify cost offsets if applicable
- ☐ Assess the likelihood that the treatment will be utilized.
- ☐ Model the impact of utilization management requirements with and without a contract.
- ☐ Assess the overall budget impact.
- ☐ Consider the budget impact of a traditional contract versus an innovative contract
- ☐ Consider other tools already in place in the organization that would address the treatment's cost.
- ☐ Assess the resources needed to implement the contract.
- ☐ Using results from the steps above, assess the overall financial impact of the product under the various scenarios.
- ☐ Assess the legal and regulatory implications of engaging in an innovative contract.
- ☐ Assess the contract's potential impact on other stakeholders.
- ☐ Prepare internal stakeholders to make a decision, educating them on innovative contracts if needed.
- ☐ If the organization chooses to proceed with an innovative contract, prepare for the contract design, negotiation, and implementation.

Organizations will also require internal resources to negotiate, implement, and maintain innovative contracts. Before entering a contract, organizations should carefully consider its technical feasibility. Third parties may be available to support assessment, design, and implementation; these resources may be particularly helpful for smaller organizations .

Other questions to consider include: What's the appetite within the organization for an innovative contract? What areas of potential alignment might be identified between innovative contracts and other organizational strategies and initiatives, such as improving health equity and access to novel products?

MOVING FORWARD FOLLOWING ASSESSMENT

Once an organization makes the decision to engage in an innovative contract, the next steps include more in-depth design of the contract's structure. See our prior briefs about key terms for payment innovation and innovative contracting 101 for an introduction to contract models. In addition, the organization

must consider how to implement and execute the contract , including what resources would be required in both the short- and long-term and external resources or third parties that could aid in execution.

Future Implementation Briefs will go into more detail about designing an innovative contract and about the processes for implementation and execution.

SOURCES

Paying for Cures Toolkit: Individual Indication workbook

Paying for Cures Toolkit: Selecting precision financing solutions

Value Based Contract Impact Assessment Model (VBCAM)

Implementation Brief: Innovative contracting 101

Implementation Brief: Key terms for payment innovation