CATALYST IMPLEMENTATION BRIEF

Innovative contracting 101

This brief provides an introduction to innovative contracts, or value-based contracts, which may be used to facilitate access to innovative, high-cost treatments. These contracts can address uncertainty around treatments and lower a payer's risk to cover these treatments. However, they require preparation and care from developers and payers to successfully design and implement.

What's covered

- ☑ Why you should consider innovative contracts and who should be involved
- ☑ How to structure the contract, and what their key elements are
- ☑ How to match contract types with risks
- ☑ How to approach negotiations

WHY CONSIDER AN INNOVATIVE CONTRACT?

Innovative contracts meet the needs of different stakeholders in addressing the risks associated with drugs and medical products. Developers and payers generally consider using these contracts when a new product possesses uncertainty around the treatment's real-world performance, durability, actuarial risk, high up-front cost/payment timing, and other factors. These contracts may also be called by other similar terms, as discussed in our key terms brief.

In some cases, payers may not cover a novel treatment without an innovative contract in place to protect against uncertainties. The contract may thus serve to reduce barriers to patient access and improve the quality of care for patients. However, these contracts can take significant resources to design and implement; they must be considered with care. A future brief will provide further guidance for evaluating whether an innovative contract is an appropriate solution for a particular product.

WHO ARE THE KEY PARTIES?

Innovative contracts are typically agreements between developers (also called manufacturers) and payers.

For the **developer**, utilizing an innovative contract can yield faster or expanded access to a therapy, as more patients will be able to receive the product when performance and financial uncertainties are addressed for payers. These contracts can also offer opportunities for developers to align payments with the value of a new therapy, such as by receiving payments over time or timed with positive outcomes for patients.

For the **payer**, utilizing an innovative contract can mitigate the risks associated with product performance and the uncertainty of reduced long-term costs for a given patient population. Some payers, such as private payers and those that cover larger populations, may have the capacity to negotiate and implement innovative contracts internally, while others may require additional resources, such as the support of third-party vendors.

Self-insured employers may be able to coordinate participation in an innovative contract with their broker or insurance carrier. Public payers may utilize resources from CMS, which is working to facilitate innovative contracting among Medicaid plans.

While developers and payers are the primary stakeholders in innovative contracting, consideration must also be given to providers and patients to ensure that a contract meets the goal of facilitating access to a new treatment. Providers and payers also play significant roles in tracking a treatment's outcomes over time; the resources needed for this tracking may be incorporated in contracts.

HOW DO YOU STRUCTURE THE CONTRACT?

The first step in designing an innovative contract is identifying the risk that you seek to address, followed by selecting a contract structure that will address this risk.

For example, to address performance risk, a developer and payer may design a contract in which a refund will be paid if the treatment fails to meet specified outcomes measures. Or, to address payment timing risk for one-time durable treatments, the payer may pay for a treatment over

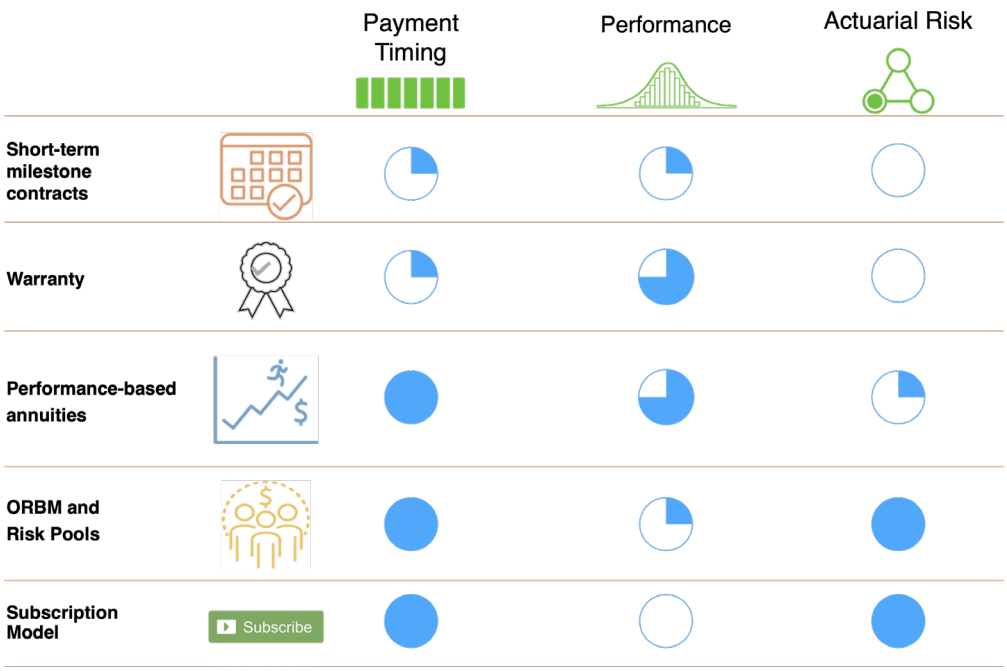
multiple years rather than one upfront payment. Or, to attain certainty around Medicaid Best Price, the developer may propose a warranty model; see the white paper about this model for further details.

Contract structures may include:

- Outcomes-based or milestone-based contracts
- Warranties
- Performance-based annuities
- Therapy/disease risk pools carve-outs
- Subscription models

See the key terms brief for further detail on these contract types.

Figure 1: Innovative contract structures, matched with their ability to address key risks. The blue circles represent the proportion of the associated challenge addressed.



WHAT ARE THE KEY ELEMENTS?

When crafting an innovative contract, there are multiple elements to consider:

- Covered product: The drug or medical product to which the contract will facilitate access.
- Type of contract: The structure used for the contract; see options above.
- Duration of contract: Length of time that the contract will be in effect.
- Eligible patient population: Patients with a specific disease indication for whom the drug or product may be effective, generally based on clinical trial results, real-world evidence, and/or FDA label. This should also address what happens when a patient leaves the payer plan.
- Site of care: Where patients receive the drug. In some cases, contracts may specify that a drug must be administered in a Center of Excellence or a different specialized center.
- Outcomes measures: Metrics that will be used to evaluate the treatment's performance. Contracts should include specific, measurable definitions of failure.
- Data source for outcomes: This can include clinical data from providers, insurance data from payers, or other sources to which stakeholders may have access.
- Data aggregation and analysis methodology: The process used to compile outcomes data, analyze the results, and identify success or failure to meet outcomes measures. Third-party vendors may assist with this process.
- Timeframe for outcomes data collection, or measurement period: How often are outcomes data aggregated and analyzed? For example, a three-year contract may include data collection every six months.
- Adjudication: Process for raising and resolving concerns relative to outcome measures. This may include opportunities to provide additional data. Disputes generally have specific timeframes in which they can be utilized.
- Payment timeframe: Timing for payers to deliver payments to developers, and/or for developers to deliver rebates.
- Payout or rebate: Dollar amount or percentage of product cost that will be returned to payer for product failure to achieve outcome criteria.
- Audit rights: Process for auditing records, if deemed necessary.
- Agreed-upon utilization management or medical policy: Process for determining patient eligibility for coverage and reimbursement.

HOW DO YOU APPROACH NEGOTIATION?

- The discussion process can begin at any time. Beginning this process early, even prior to regulatory approval, will allow more time for consulting different stakeholders and negotiating terms.
- Developers may choose to consult with payers, providers, and patient groups about potential contract terms to design the contract with consideration for effective implementation.
- Negotiation of contract terms primarily occurs between a developer and payer. If a warranty model is used, third-party insurers are also involved in the negotiation.
- Developers may offer a set contract template to payers. This approach has the benefit of limiting variables for negotiation but may not be as attractive to payers that would like to negotiate terms.
- It is important for developers and payers to agree on acceptable outcome measures for the contract negotiations to go as smoothly as possible.
- Tools such as the Value Based Contract Impact Assessment

Model may help payers and developers evaluate the potential financial impacts of different contract terms.
- Developers should consider regulatory requirements, such as impact on Medicaid Best price and other government reporting.
- Developers and payers should consider the process for outcomes data collection, aggregation, and adjudication. They should also consider the role of third parties to manage the data process and other aspects of contract implementation.
- Developers and payers will need to determine the administrative cost of the contract and define each party's responsibility for payment of these costs. This should be agreed to and included in the contract.
- Processes for contract amendments, assignments, and terminations should also be defined during the negotiation.

CONTRACT EXAMPLES

Treatment	Stakeholders	Risks addressed
Zynteglo, gene therapy for beta-thalassemia	Bluebird Bio	Bluebird Bio offers an outcomes-based contract with reimbursement if the therapy fails to achieve specified outcomes measures, addressing performance risk.
Alunbrig, non-small cell lung cancer treatment	Takeda, Point32Health	Takeda will offer a rebate to Point32Health if a patient stops utilizing the treatment due to efficacy or tolerability, addressing performance risk.
Jardiance, oral type 2 diabetes medication	Boehringer Ingelheim, UPMC Health Plan	The contract links payer reimbursement to clinical outcomes across total costs of care for all health plan patients with diabetes treated with the medication, addressing performance risk.
Zolgensma, gene therapy for children with spinal muscular atrophy	AveXis (Novartis), Accredo	Through the specialty pharmacy Accredo, AveXis offers a pay-over-time option over up to five years for this therapy, addressing payment timing risk.

REFERENCES

Implementation brief: Key terms for payment innovation

FoCUS Paying for Cures Toolkit

Tools for Implementation of Precision Financing Solutions Within Medicaid Plans – Worksheet for negotiating value-based contract

National Association of Managed Care Physicians (NAMCP) Value-Based Pharmaceutical Contracts (VBPCs)-Facilitation and Execution Considerations

Warranty Model: A potential precision financing solution for durable cell and gene therapies

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