CATALYST IMPLEMENTATION BRIEF

Key terms for payment innovation

This brief provides definitions of key terms that are often used in discussions about designing and implementing innovative payment solutions. It offers an overview of solution models, types of risk, reimbursement considerations, and more. This terms brief is intended as a foundational reference for readers who may be newer to this field.

What's covered

- Introductory terms
- How we describe solutions
- Types of risk
- Types of innovative contracts
- Contract examples
- Reimbursement terms
- Additional terms

INTRODUCTORY TERMS

Traditional contracts: Contracts providing discounts and rebates based on negotiations between the manufacturer and payer for coverage and reimbursement of a product. These may be based on access positioning of the product and/or volume of product used. This is the prevailing approach to payer contracting.

Value-based care: A model for delivering healthcare that reimburses stakeholders based on how a therapy or provider performs, relative to real-world metrics over a defined time period.[1]

Payment innovation: An area of healthcare payment focused on developing novel methods of paying for products that better align payment with a product's value to patients. It may also address financial challenges relative to very high-cost treatments.

HOW WE DESCRIBE SOLUTIONS

Experts involved in payment innovation may utilize several similar terms to describe the financing solutions used to meet the needs of different stakeholders in addressing the risks associated with durable, high-value drugs and medical products.

These terms include:

- Precision financing solutions
- Value-based purchasing
- Innovative contracts
- Value-based contracts
- Value-based agreements
- Alternative payment models

These solutions generally involve contracts or agreements that align aspects of payment for a product, such as timing and rebates, with predetermined outcomes metrics or milestones. As such, these solutions aim to reward products that improve patient health according to real-world measures. The contracts are generally agreements between payers and developers, but other stakeholders may be involved with designing and implementing the agreements.[2]

TYPES OF RISK[3]

These terms describe the types of risk that precision financing solutions seek to address.

Actuarial risk: Generally, this refers to the risk assumptions actuaries incorporate into models used to price specific insurance policies. In the context of high-value, durable therapies, a key risk for an insurance plan is the accuracy of predicting how many patients it will have on such therapies.

Performance risk: This risk refers to the inability to accurately predict how well a product works for a given patient or group of patients. It includes two components:

- Immediate real-world effectiveness of the therapy;
- Durability, or real-world effectiveness over time.

Payment timing risk: This risk refers to payers paying for a high-value therapy upfront, when its benefits accrue over time as the patient may no longer be a member of the plan. It may also refer to cash flow demands when a new high-cost treatment for a prevalent condition enters the market and multiple patients seek reimbursement for treatment at the same time.

TYPES OF INNOVATIVE CONTRACTS[4]

Contracts based on a product's real-world results:

Outcomes-based contracts: Contracts that link payment for a product with real-world outcomes representing whether the treatment meets or fails expectations for a patient's health. Payers make

upfront payments and developers provide refunds if specific payment outcomes are not met.

Risk-based contracts: Contracts that link payment to a distribution of risk for the product's performance to fail, assuming that performance will vary for different patients.

Contracts based on financial solutions:

Payment over time/installment financing: Payers pay for one-time durable therapy products over multiple years, rather than in one upfront payment.

Subscriptions: Developers and payers set a specified "subscription" cost to provide a product to one patient or a patient population, up to a set total cost or volume, determined in negotiation.

Therapy/disease risk pools carve-outs: Payers separate out a particular high-risk population with a certain disease or that is eligible for a certain therapy to form a risk pool, sometimes to be managed by another party with greater capacity to manage the risk.

Hybrid contracts based on both results and financial solutions:

Performance-based annuities: Multi-year agreements between payers and developers that include an upfront payment by the payer of a specified portion of the product cost, followed by a commitment to further payments from the payer, triggered by patient outcomes being achieved, every year for a defined number of years.

Warranties: Third party insurance policies issued to payers by developers, promising to repay healthcare claims or treatment costs resulting from less-than-expected performance of a medical product. The premium paid by developers for the warranty is included to calculate Medicaid Best Price.

REIMBURSEMENT TERMS[6]

Average Sales Price (ASP): A drug pricing method for drugs and biological products covered under Medicare Part B. Developers submit ASP data for their products to CMS, whose payment for providers is 106% of the ASP, less applicable beneficiary deductible and coinsurance. Provider payment may be different for commercial payers.

Average Manufacturer Price (AMP): The average price paid to developers by U.S. wholesale drug purchasers that purchase drugs directly from developers (such as retail pharmacies), for a specific product.

Rebate: A discount that occurs after drugs are purchased from a developer, involving the developer returning some of the price to the purchaser. Types of rebates include:

- **Formulary access rebate:** A discount paid by the manufacturer to the payer as a result of negotiations around formulary coverage and preference status
- **Volume-based rebate:** A discount paid by the manufacturer to the payer tied to the volume of drug purchased.
- **Medicaid mandatory rebate:** A provision of the Medicaid Drug Rebate Program that requires a drug manufacturer to enter into a national rebate agreement with the Secretary of the Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's

CONTRACT EXAMPLES[5]

Type of contract	Stakeholders	Description
Outcomes-based contract	Bluebird Bio, Michigan Medicaid	This agreement links payment for the sickle cell disease gene therapy Lyfgenia to hospitalizations related to vaso-occlusive events, a metric available in claims data. Bluebird is also in ...discussions with other state Medicaid agencies.
Payment over time/installment financing	Novartis, Accredo Health plan clients	Through this agreement, for the spinal muscular atrophy drug Zolgensma, specialty pharmacy Accredo pays Novartis company AveXis upfront for the full cost of the drug and health plans pay Accredo over up to five years. Payment rates and time periods are subject to negotiation.
Warranty	Pfizer/AIG insurance, payers and patients	Under this warranty program for the drug PANZYGA, which treats chronic inflammatory demyelinating polyneuropathy (CIDP), Pfizer offers refunds to both patients and payers when providers discontinue treatment for clinical reasons. The warranty applies up to a patient's first four treatments.

drugs. For brand name drugs, the manufacturer must pay states a rebate equal to the greater of either 23.1% of Average Manufacturer Price (AMP) (or 17.1% of AMP for certain pediatric and clotting drugs) or the difference between AMP and the best price manufactures offers any other purchaser. This best price is referred to as **Medicaid Best Price**.

- **Medicaid Supplemental/additional rebate:** These rebates are set through amendments to state Medicaid plans that allow states to negotiate additional rebates (over and above the mandatory rebate). Manufacturers may pay supplemental rebates for placement on a preferred drug list or as part of a value-based purchasing agreement.

ADDITIONAL TERMS

Eligible population: The patient population that is eligible to receive a particular treatment, often based on the populations included in clinical trials for this treatment.

Effectiveness of therapy: The success of a drug or other medical product at treating a given disease, as measured in real-world outcomes collected during clinical care or through insurance claims.

Outcomes: A specific result or effect that can be tracked and measured. Examples of data sources for outcomes include claims, medical records, and provider collection encounters specific to outcomes tracking.

Portability: The risk of a patient leaving an insurance plan following a high-cost therapy while an outcomes-based contract is still in progress. These patients are generally lost to follow-up.

REFERENCES

1. AMCP lexicon paper
2. Paying for Cures Toolkit Glossary, AMCP lexicon paper
3. Paying for Cures Toolkit Glossary
4. Ibid.
5. Lyfegen database and company websites: Bluebird Bio, Novartis, Pfizer
6. Paying for Cures Toolkit Glossary, AMCP lexicon paper, CMS

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