

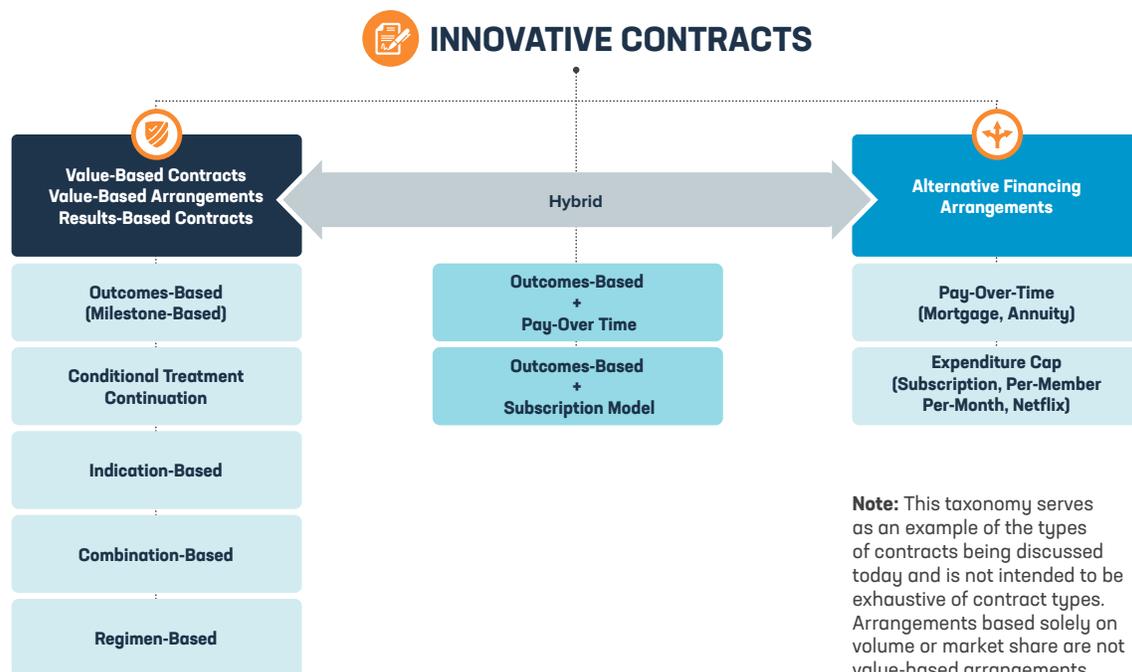
Innovative Contracting: Opportunities and Challenges

We are in a new era of medicine where breakthrough science is transforming patient care, but these innovations are meaningless if patients can't access them. Key health care stakeholders are working together to move the United States towards a more value-driven health care system in which payers, providers and biopharmaceutical companies work together to improve patient outcomes and reduce costs without sacrificing the quality of care. Innovative contracts are one example of a collaborative solution that can help increase patient access to lifesaving care.

Innovative contracts—also known as value-based contracts or alternative financing arrangements—for biopharmaceuticals are voluntary arrangements between manufacturers and other entities, such as health plans or risk-bearing providers, in which the price or price concession for a prescription medicine is linked to value as determined by the contracting entities. These arrangements have the potential to lower costs through voluntary, market-based negotiations between manufacturers and payers—as opposed to government or other centralized value assessment.

There are currently almost 100 publicly announced contracts—and counting—with nearly 50 brands and 30 medicine producers participating in the United States. Nearly 30 conditions are covered by a wide variety of innovative contracts, including multiple sclerosis, diabetes and cancer. However, this only represents a small fraction—as little as 30% according to one study—of the contracts in use, as most contracts are not publicly announced.ⁱ

According to one survey, nearly half of U.S. payers surveyed expressed a belief that wider implementation of innovative contracts could lead to lower patient out-of-pocket costs across small molecule, biologic, cell and gene therapies.ⁱⁱ This echoes what biopharmaceutical companies have said about these innovative contracts, building off recent studies that demonstrate the potential impact value-based approaches can have on improving patient health outcomes, decreasing payer costs and lowering patient out-of-pocket spending. One pharmacy benefit manager (PBM) has reported annual savings of \$4.3 billion on medicines through the use of innovative contracts.ⁱⁱⁱ



Many innovative contracts can be beneficial to patients as they can help lower out-of-pocket costs and increase access while providing savings for the health system.

Innovative contracts can help improve patient outcomes. This could occur if payers are able to provide broader access to innovative medicines, under contracts with biopharmaceutical companies that take on increased risk for outcomes. It could also occur as these contracts can allow payers or biopharmaceutical companies to do more to support appropriate patient use of medicines. One analysis found 58% of payers that use results-based contracts saw improved patient outcomes.^{iv}

Innovative contracts can help reduce medical costs. Supporting better use of medicines through innovative contracts can reduce spending on medical services by reducing hospitalizations, emergency room visits or other costly results of poorly controlled disease.

For example, if innovative contracts lower the burden of diabetes in the United States by 5%, the United States could save more than \$12 billion annually.^v Another analysis found that 45% of payers believe that wider implementation of innovative contracts could lead to lower patient out-of-pocket costs.^{vi}

Innovative contracts can help reduce the out-of-pocket costs of medicines for patients. In value-based programs between biopharmaceutical companies and pharmacy benefit manager Express Scripts, patients taking cholesterol-lowering medicines saved nearly \$800,000 out of pocket in 2020. And in Medicare, after a value-based arrangement for a cardiovascular medicine went into effect, patients' out-of-pocket costs were reduced to just \$10 a month, on average. These patients used to pay, on average, over \$40 for a month-long supply of the medicine.^{vii}

Unfortunately, unclear government rules and regulations can create uncertainty around these contracts, which may deter biopharmaceutical companies, insurers and risk-based providers from adopting them. One key barrier, the lack of clarity for engaging in communications in facilitating innovative contracts, was addressed by FDA in 2018. But other federal policies - lack of clarity around the federal Anti-Kickback Statute - still need further clarification for more effective use of innovative contracts. The Centers for Medicare & Medicaid Services new rule allowing "multiple" best prices could help address some issues with government price reporting requirements for innovative contracts,^{viii} but without further clarification and modernization of current anti-kickback guidance, the full benefits of innovative contracts may not be realized.

ADDRESSED BARRIER

Lack of Clarity for Engaging in Communications that Facilitate Innovative Contracts

BARRIER: Lack of clarity in the Food and Drug Administration (FDA) regulations and policy regarding biopharmaceutical company communications presented obstacles to communicating health care economic information critical to negotiating innovative contracts.

ACTION: In 2018, the FDA released two guidance documents that provide clarity on how biopharmaceutical firms may communicate certain information, including health care economic information, consistent with FDA regulations.

REMAINING BARRIERS

Lack of Clarity in the Anti-Kickback Statute

Dated and Complex Price Reporting Rules

Addressing remaining barrier to innovative contracts would support an innovative, market-based solution that could help provide patients with more affordable access to new medicines. PhRMA is also monitoring the impact of the Medicaid rule and how it impacts contracting between states and manufacturers. Price reporting may remain a barrier, especially for products that require multiple treatments.

To learn more, visit [PhRMA.org/value-collaborative](https://www.phrma.org/value-collaborative).

i N Mahendraratnam. *Value-Based Arrangements May Be More Prevalent Than Assumed*. AJMC. February 13, 2019.
ii Verpara. *Understanding the Patient and Caregiver Benefit of Value-Based Agreements in the U.S.* October 2020.
iii Express Scripts. *SafeGuardRx Saved Enrolled Plans \$4.3 Billion in 2019*. March 2020.
iv Avalere. *More than Half of Health Plans Use Outcomes-Based Contracts*. October 2019.
v PhRMA. *Value-Based Contracts May Lower Patients' Out-of-Pocket Costs by 28 Percent*. February 2018.

vi Verpara. *Understanding the Patient and Caregiver Benefit of Value-Based Agreements in the U.S.* October 2020.
vii PhRMA. *Guest post: Value-based agreements can improve outcomes and even save patients money at the pharmacy counter*. 2019.
viii 85 Fed. Reg. 8700, Dec. 31, 2020.