Value-Based Contracting in Pharma: Models & Challenges

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Executive Summary

Value-based contracting (VBC) in pharmaceuticals – also called outcomes-based or performance-based contracting – ties the price or reimbursement of a drug to its real-world clinical or economic performance. Under such agreements, drug manufacturers agree to refund or rebate part of the cost if the therapy fails to achieve agreed-upon outcomes in patients (www.ajmc.com) (www.contractpharma.com). This approach has gained attention amid rising drug prices, especially for high-cost specialty and gene therapies, as a way to align payment with value (www.ajmc.com) (www.contractpharma.com). Proponents argue VBC can improve access to innovative treatments while sharing risk between payers and manufacturers (www.contractpharma.com) (www.pharmexec.com). Critics counter that evidence is limited: early studies find outcomes-based deals apply to only a few drugs and have not demonstrably lowered overall drug spending or improved quality (pubmed.ncbi.nlm.nih.gov) (www.researchgate.net). Many agreements remain confidential, and operational challenges (data tracking, administrative complexity, multi-drug regimens) often hamper implementation (www.ajmc.com) (www.pharmexec.com). Nonetheless, stakeholders – including payers, policymakers, and pharma companies – continue to explore and pilot these contracts in diverse markets (US, Europe, etc.) to manage costs and justify premium prices by "putting money where the mouth is" (www.ajmc.com) (www.pharmexec.com). This report provides a detailed analysis of value-based pharmaceutical contracting, including definitions and models, stakeholder perspectives, empirical evidence, case studies, challenges, and future directions. Key findings include:

- **Definitions and Models:** VBC encompasses a range of contracting models from *financial-risk* agreements (e.g. capped spending) to *outcomes-based* schemes where payment is tied to patient outcomes or performance guarantees (www.mckinsey.com) (www.contractpharma.com). Outcomes measures can include biomarker levels, hospitalization rates, adherence, or broader clinical endpoints (www.ajmc.com) (www.mckinsey.com). Contracts often specify thresholds (e.g., X% of patients achieve a target) that determine if rebates or refunds are triggered. Some models (such as "subscription" or "Netflix" agreements) set flat fees for unlimited treatment access, as seen in hepatitis C treatment programs (www.fiercepharma.com) (www.fiercepharma.com). Table 1 below summarizes major contract types.

- **Drivers and Rationale:** Escalating specialty drug costs (often hundreds of thousands per patient) and pressure from payers and regulators have spurred interest in VBC (www.ajmc.com) (www.pharmacytimes.com). Payers see VBC as a mechanism to limit spending on therapies that underperform, while manufacturers view it as a way to smooth acceptance of high launch prices by guaranteeing value (www.contractpharma.com) (www.pharmexec.com). The emerging era of precision medicine and gene therapies – with cures offered for large sums – intensifies the need for innovative payment models. Stakeholders also highlight the potential for real-world evidence (RWE) gathered through VBCs to inform future care.

- **Empirical Evidence:** To date, only a small number of publicized outcomes-based contracts exist. A McKinsey analysis (2017) identified ~200 innovative pharma arrangements globally since 1994, of which only ~50 were U.S. deals (www.mckinsey.com). Most contracts to date have targeted oncology, cardiology, diabetes, and other specialties, often associated with expensive biologics or novel therapies (www.ajmc.com) (www.mckinsey.com). Examples include a landmark 2007 UK "money-back guarantee" for J&J's Velcade in myeloma and U.S. deals (2009) linking diabetes drug rebates to blood sugar outcomes (www.ajmc.com) (www.ajmc.com). Nonetheless, systematic evaluations have found **no evidence** so far that these contracts reduce overall spending or improve outcomes (pubmed.ncbi.nlm.nih.gov) (www.researchgate.net). The scope of VBC remains limited: arguably only a narrow subset of drugs with measurable outcomes have been covered.

- **Case Studies:** Well-known examples provide practical insights. One early model was J&J's 2007 Velcade agreement with the UK NHS: if myeloma patients failed to achieve a ≥50% reduction in a biomarker by Cycle 4, J&J provided full-cost rebates (typically via free doses) (www.ajmc.com). </current_article_content>In the U.S., Merck's 2009 deal with Cigna tied rebates on diabetes pills (sitagliptin) to patients' HbA1c improvements and adherence (www.ajmc.com). European countries (Italy, Spain) and U.S. states (Washington, Louisiana) have also implemented innovative schemes, from outcomes guarantees for epilepsy drugs in France to subscription models for hepatitis C eradication in U.S. Medicaid (www.mckinsey.com) (www.fiercepharma.com). Tables 2 and 3 present selected contract examples and outcomes.

- **Barriers and Challenges:** Numerous hurdles impede widespread adoption. Clinically: many diseases lack clear, short-term outcomes or involve combination therapies, complicating attribution of success to a single drug (www.ajmc.com) (www.pharmexec.com). Operationally: payers often lack the data infrastructure to track patient outcomes across care settings, and privacy laws (e.g. HIPAA) can limit data sharing (www.pharmexec.com) (www.pharmacytimes.com). Legally: U.S. regulations like Medicaid "best price" rules historically discouraged rebates, though recent CMS proposals (2020) aimed to unwind these barriers (www.cms.gov) (www.cms.gov). Contract complexity and negotiation costs remain high, deterring many plans from attempting VBC (www.pharmexec.com) (www.contractpharma.com). Indeed, surveys of payers and manufacturers cite the difficulty of defining appropriate metrics, patient eligibility, and financial terms as key obstacles (www.ajmc.com) (www.pharmexec.com).

- **Expert Perspectives:** Analysts are divided on VBC's promise. Some industry experts stress that manufacturers should "bet on outcomes" and become "solution providers" by sharing risk (www.pharmexec.com) (www.contractpharma.com). Pharmaceutical leaders (e.g. Novartis CEO) publicly advocate for paying only for real-world value (www.pharmacytimes.com). Conversely, health policy researchers caution that outcomes contracts alone won't fix drug affordability: they may shift costs rather than reduce them, and might serve more as "access tools" for expensive therapies than true savings programs (pubmed.ncbi.nlm.nih.gov) (www.researchgate.net). One analysis concluded these contracts "have not proven successful" in Italy and carry "questionable" benefit (pubmed.ncbi.nlm.nih.gov). Ongoing pilot programs (in Medicare, Medicaid, and private plans) aim to test feasibility and generate evidence (www.contractpharma.com) (pubmed.ncbi.nlm.nih.gov).

- **Future Directions:** The policy landscape is evolving. Recent U.S. regulations (e.g. Inflation Reduction Act) impose some price negotiation, but separate initiatives (from CMS and state Medicaid programs) continue to encourage VBC pilots (www.cms.gov) (www.contractpharma.com). Advances in data analytics and interoperability could reduce administrative burdens over time (www.pharmacytimes.com) (www.pharmexec.com). As more "curative" therapies emerge, payers and politicians remain keen to explore alternative financing (e.g. installment payments, annuities, subscriptions). Overall, value-based contracting is likely to expand, but its actual impact on costs, access, and health outcomes will depend on rigorous evaluation.

Introduction

The escalating costs of novel pharmaceuticals have placed intense pressure on health systems, payers, and patients worldwide (www.ajmc.com) (www.pharmacytimes.com). In the United States, for example, retail drug spending reached $675 billion in 2021, with specialty medicines (often biologics and advanced therapies) accounting for over half of total expenditure (www.pharmacytimes.com) (www.fiercepharma.com). High-priced cures for rare diseases (car-T cell therapies, gene therapies) – often exceeding $1–2 million per patient – amplify concerns about value and sustainability. In this climate, **value-based contracting (VBC)** has been proposed as a market-based solution: aligning the payment for drugs with the **health outcomes they deliver**. Rather than paying solely on a *per-prescription* basis (volume), a value-based contract ties reimbursement to agreed performance targets (www.ajmc.com) (www.pharmexec.com). If the therapy succeeds, the manufacturer earns full payment; if it falls short, the company may provide rebates, price adjustments, or additional support.

Broadly, *value-based contracting* encompasses several models. Outcomes-based or *performance-based* agreements are the most ambitious: they define clinical end-points (e.g. HbA1c reduction, hospitalization avoided) and financial incentive: the manufacturer pays back or discounts the drug cost for each patient who does not achieve the target (www.ajmc.com) (www.contractpharma.com). Other models focus on economic metrics: for example, an agreement might guarantee that the total spending on a cohort of patients does not exceed a cap (risk-sharing) (www.mckinsey.com). Subscription or "Netflix" models, recently adopted by states for hepatitis C drugs, involve a flat fee for unlimited access over time (www.fiercepharma.com) (www.fiercepharma.com). These arrangements are all variations on the theme of *"paying for value, not just volume."*

The shift toward value-based/payment (VBP) models has a broader context beyond pharmaceuticals. In health care generally, there has been a move from fee-for-service to outcomes-oriented payments – e.g. accountable care organizations and bundled payments (www.intechopen.com) (www.pharmexec.com). Over the past two decades, the U.S. Medicare program and private insurers have implemented pay-for-performance initiatives for hospitals and physicians (www.intechopen.com) (www.pharmexec.com). However, applying the concept to pharmaceuticals is relatively novel. Drugs have unique status: they undergo separate pricing and reimbursement reviews (e.g. health technology assessments) and face different regulations

(FDA approval, Medicaid rebates) compared to services. The idea of *directly linking a drug's price to its outcomes* challenges traditional purchasing practices (flat discounts, rebates, formulary tiers) and requires new tools: real-world data tracking, risk-adjusted pricing, and contractual mechanisms akin to insurance.

Historically, most drug payments have been determined by list prices negotiated with insurers/Pharmacy Benefit Managers (PBMs), with rebates provided after the fact based on market share. This volume-based model does not penalize ineffective treatments: a drug that fails in many patients still generates revenue by higher sales **unless** payers restrict access. Under value-based contracts, by contrast, the manufacturer *shares the risk*. If the drug fails to perform, the manufacturer may have to reimburse or provide additional support. As one expert put it, outcomes-based contracting is about "betting on outcomes" rather than volume (www.pharmexec.com).

This paradigm shift has gained momentum partly due to public and political scrutiny of drug pricing. High-profile price increases (e.g. Daraprim's 5,000% hike) and the entry of extremely pricey cell/gene therapies have focused attention on affordability (www.pharmexec.com) (www.pharmacytimes.com). In 2020, for example, CMS explicitly sought to *facilitate* outcomes-based payment models by easing Medicaid reporting requirements, recognizing that old rules (e.g. Medicaid Best Price) inadvertently discouraged risk-sharing contracts (www.cms.gov) (www.cms.gov). Similarly, state Medicaid programs (e.g. California, Louisiana, Washington) have adopted innovative agreements to manage spending on curative hepatitis C drugs (www.fiercepharma.com) (www.fiercepharma.com).

This report examines the concept, practice, and evidence for value-based contracting in pharmaceuticals. We define key terms and models (Section II), survey the rationale and stakeholders (III), and analyze data on adoption rates and outcomes (IV). We present illustrative case studies (V), discuss challenges (VI), and conclude with implications for the future (VII). Throughout, we cite up-to-date research, news and policy sources to provide a balanced, evidence-based perspective.

Types and Models of Value-Based Pharmaceutical Contracts

Value-based pharmaceutical contracts can be categorized along several dimensions. Table 1 below summarizes common types, with examples. A more detailed breakdown follows.

Model Type	Description	Example
Outcomes-based (Performance)	Reimbursement tied to patient outcomes or clinical targets. Manufacturer provides rebates/refunds for patients who fail to meet pre-specified outcomes.	*J&J Velcade (England, 2007)*: 50% paraprotein reduction test by 4 cycles; failure triggers reimbursement (www.ajmc.com).

Model Type	Description	Example
		Merck Januvia (USA): Rebates to Cigna if diabetic patients' HbA1c not lowered by target (www.ajmc.com).
Financial (Budget) Risk-Sharing	Payment based on overall spending metrics (capitation, Caps). Not directly linked to clinical outcomes. Manufacturer shares financial risk if total spend exceeds threshold.	*Novartis Lucentis (UK)*: NHS caps total injections at 14 per patient; manufacturer covers additional doses beyond cap (www.mckinsey.com).
		Generic HCV cure subscription (e.g. Louisiana Medicaid): Flat payment (~$58M/year) for unlimited hepatitis C treatments (www.fiercepharma.com).
Indication or Population Pricing	Differential pricing by indication or patient subgroup. Price per unit varies according to condition's expected value. Often unilateral (not typically negotiated).	*Segmentation*: Novartis Kisqali: different price or formulary status by breast cancer subtype (www.mckinsey.com).
"Value Guarantee" / Warranty	Drug is sold at full price but comes with a "warranty": e.g. money-back if patient discontinues early. Manufacturer purchases insurance or underwrites risk.	*Pharmacy warranty programs (2022)*: Oncology "warranties" where manufacturers refund if therapy discontinued early (www.pharmacytimes.com).

Table 1: Examples of value-based pharmaceutical payment models (selection).

Outcomes-based or Performance Contracts. These are the paradigmatic value-based deals: the drug's price is conditional on achieving agreed clinical results. Under these contracts, payers reimburse at the list/unit price for treated patients, but manufacturers refund partial or full payment for cases where the drug "fails." Often, the contract defines a target metric (laboratory value, clinical endpoint, etc.) and a threshold: e.g. the drug must achieve remission or biomarker improvement in a certain fraction of patients, or else refunds/sales adjustments trigger (www.ajmc.com) (www.mckinsey.com). For instance, in 2007 Johnson & Johnson guaranteed the performance of its myeloma therapy Velcade in the UK: if patients did not achieve a ≥50% drop in a cancer marker (M-protein) by cycle four, J&J reimbursed the full drug cost (www.ajmc.com). Similarly, in 2009 Merck tied rebates on its diabetes pills (Januvia/sitagliptin) to patients' blood sugar control and adherence; improved outcomes triggered deeper discounts (www.ajmc.com). Table 2 (below) lists notable outcomes-based contracts (see also Case Studies). Clinically, outcomes-based models may measure *intermediate markers* (blood pressure, LDL-cholesterol) or hard endpoints (hospitalization, fracture).

Financial or Budget Cap Contracts. A simpler class of contracts decouples payment from any outcome, tying it instead to a financial metric. Commonly, a cap is set on total spending or per-patient cost. These arrangements guarantee that the payer will not exceed a specified expenditure level: if patients consume more drug or incur more treatment costs than forecast, the manufacturer covers the excess. Such capitation deals effectively insure the payer against high utilization. For example, the UK's National Health Service negotiated with Novartis so that Lucentis (for macular degeneration) was only reimbursed for the first 14 injections; beyond that, Novartis covered additional doses (www.mckinsey.com). Similarly, some states and providers have entertained fixed-fee population models for hepatitis C ("subscription" contracts) where

the payer pays a flat annual fee for unlimited cure drugs, regardless of how many patients are treated (www.fiercepharma.com). These models manage budget predictability but do not explicitly reward better outcomes – they focus on cost containment through volume risk sharing (www.mckinsey.com) (www.fiercepharma.com).

Indication/Population-Specific Pricing (Segmentation). Under this approach, a manufacturer sets or negotiates different prices for different indications or patient groups. While often unilateral (a manufacturer publicly announces a special price for a subgroup), some negotiated deals may tie price to patient selection. For example, if one biomarker profile predicts stronger drug efficacy, the drug might carry a higher price in that subgroup. This concept was described as "segmentation" by McKinsey analysts (www.mckinsey.com). (Example: Novartis marketed its breast cancer drug Kisqali at different volumes for certain subtypes.) Indication-based pricing is not inherently outcomes-driven, but aims to align per-patient price with expected value in that indication.

Hybrid and Other Models. Variations abound. Some contracts combine outcomes and financial elements (e.g. sharing savings if outcomes exceed benchmarks). Subscription or *"Netflix"* models treat the drug like a subscription service: the payer pays a gross fee for broad access. In the U.S., Louisiana and Washington state agreed to pay ~$290 million and $321 million respectively over 5–4 years for unlimited access to hepatitis C cures for Medicaid populations (www.fiercepharma.com). These programs aim to cure thousands of patients for a fixed budget, effectively democratizing access. Table 1 includes this category. Also, value-based contracts often include patient support services, shared data collection obligations, or outcomes monitoring.

Each model reflects trade-offs (detailed in later sections). Outcomes-based deals potentially reward innovation by linking payment to real health gains. Conversely, financial models (caps, subscriptions) offer budget control but may pay for failures as long as costs stay capped. Real-world practice often sees hybrid agreements or government-nurtured schemes (e.g. Italy mandates performance-based contracts for oncology drugs). The taxonomy above provides a framework for understanding diverse agreements.

Rationale for Value-Based Drug Contracts

Rising Drug Costs and Value Imperative

Escalating Costs. Global drug spending has accelerated, driven by specialty and biotechnology products. For instance, IQVIA data show that U.S. specialty medicines accounted for 53% of drug expenditures by 2021 (www.pharmacytimes.com). Many new therapies (gene and cell therapies, CAR-T treatments) bring transformative benefits but at multi-million-dollar price tags. High prices strain payer budgets and patient wallets: surveys report 30% of Americans skip

medications due to cost and that 60% abandon prescriptions costing >$500 (www.pharmacytimes.com). The public and policymakers have responded: legislative efforts (like the U.S. Inflation Reduction Act of 2022) now mandate Medicare price negotiations for select drugs. In this context, value-based contracts offer a market-driven way to ensure that high costs correspond with high benefit.

Risk and Uncertainty. Payers often worry about *clinical uncertainty* and *long-term value*. Traditional pricing treats all units equally, but outcomes can vary widely among patients. Pay-for-performance contracts theoretically reduce uncertainty by committing manufacturers to put "money where their mouth is" – literally refunding if performance lapses (www.pharmexec.com) (www.cms.gov). For example, a manufacturer might argue a drug "should" work for 80% of patients; an outcomes contract verifies this claim. These agreements also transfer some financial risk from the payer to the maker, aligning incentives to optimize patient selection, adherence, and monitoring. As the U.S. CMS press release notes, moving to payment based on "quantity of treatments provided" toward payment based on "quality of a drug product" can reward truly effective therapies (www.cms.gov).

Access and Innovation. Proponents assert that VBC could broaden access to costly medications. A payer might allow unrestricted formulary access if the manufacturer guarantees outcomes, rather than rejecting a drug outright for budget reasons. For instance, Dean Erhardt observed that value-contracts can keep expensive drugs on formularies in exchange for outcomes guarantees, preserving volume for manufacturers while sharing low-value risk (www.contractpharma.com). Similarly, in contexts like state Medicaid, adopting flexible contracts may expedite coverage of cures. Manufacturers may be more willing to invest in R&D if assured that payers will cover effective drugs with premium prices when tied to results (www.pharmexec.com) (www.pharmacytimes.com). On the flip side, critics warn that VBC can also be used by companies to defend high launch prices by offering rebates later (see Sec. VI).

Legislative and Market Drivers. Policy environments increasingly encourage innovative pricing. In 2020, CMS explicitly proposed easing Medicaid regulations (updating rules decades old) to permit *commercial plans and states* to negotiate outcomes-based payments without penalizing Medicaid best-price reporting (www.cms.gov) (www.cms.gov). The administration argued this would let manufacturers "put their money where their mouth is," by making rebates for unmet outcomes easier. States are also experimenting: examples include Maryland's gene therapy "subscription" models and pilot programs in state Medicaid to test performance-based payment for high-cost therapies (e.g. Novartis' Zolgensma for SMA). In Europe, governments have long used various *risk-sharing* schemes to palliate budget impact, often for new orphan and oncology drugs. For example, Italy requires pharmaceutical companies to engage in performance-based contracts for designated drug classes (www.mckinsey.com). Thus, regulatory and institutional factors are actively lowering barriers.

Shifting Stakeholder Views. Industry leaders and payers are showing interest. A survey of managed care executives found dissatisfaction with existing volume-based contracting; only 4% were "very satisfied" (www.ajmc.com). Executives from companies like Johnson & Johnson and

Novartis have publicly endorsed outcomes contracts as the coming norm (www.ajmc.com) (www.pharmacytimes.com). At the same time, payers are exploring alternatives: Kaiser Permanente rolled out pilot programs linking oncology drug costs to outcomes, and PBMs (pharmacy benefit managers) have begun negotiating such deals with drug manufacturers. Major industry analyses conclude that "innovative contracts are here to stay" and will be key strategic tools (www.mckinsey.com). In sum, the push toward value-based agreements stems from economic pressure, desire for accountability, and convergent interest among payers and pharma to demonstrate value for premium prices.

Mechanisms and Implementation

Designing an outcomes-based drug contract is complex. Key elements include defining the **eligible population**, selecting measurable **outcomes**, determining **payment triggers**, and establishing the administrative **infrastructure** for data collection and audit.

Defining Outcomes

A fundamental question is: *What outcomes count?* Ideally, hard clinical endpoints (increase in survival, reduction in hospitalizations, prevention of disease progression) would be used. However, such endpoints may take years to realize or may be influenced by many factors beyond the drug. In practice, many contracts rely on intermediate or surrogate outcomes: for example, control of HbA1c in diabetes, cholesterol levels in cardiology, or HIV viral load. Outcomes may be **individual** (patient-level) or **population** (aggregate) measures. A threshold might require that a certain percentage of patients in the program meet the target after X months, as in the Velcade case (www.ajmc.com).

Payers and manufacturers often disagree on preferred metrics: surveys note payers favor longevity and quality-of-life improvements, whereas manufacturers stress near-term efficacy measures (www.ajmc.com). In oncology, measurable tumor response might be used, while in chronic diseases adherence rates or surrogate lab values are proxies. The chosen metric must be clinically meaningful and tied to the payer's value proposition (e.g. reduced downstream costs). However, objectively capturing true *value* can be elusive. A contract that links payment to any single lab test or short-term result risks oversimplifying complex diseases (www.pharmexec.com).

Eligibility and Attribution

Contracts must specify who is included: only newly-treated patients? Those with certain prior therapy history? For example, a Novartis gene therapy for SMA (Zolgensma) might be limited to treatment-naïve infants under age 2. Eligibility criteria affect how generalizable outcomes are

and how to compare patients. Relatedly, attribution rules must be defined: if a patient discontinues early, switches drugs, or dies of unrelated causes, is that considered a treatment failure? Clarity is essential because outcomes will be audited for payment adjustments (www.pharmexec.com). Some contracts require patients to take the drug for a minimum period to count as "treated." Others adjust for adherence.

Multi-drug therapies pose a challenge: when patients are on combination regimens (common in oncology, HIV, etc.), isolating the effect of one drug is difficult (www.ajmc.com). Drug companies are generally unwilling to guarantee success when their product is one of several. For instance, making a rebate contingent on overall health improvement in multi-drug cancer regimens is problematic. Contracts often try to narrow focus to monotherapies or add-on therapies with strong mechanistic rationale.

Payment Terms and Formulas

Once targets and population are set, the contract spells out the financial terms. Typical mechanisms include:

- **Rebates or Refunds:** If outcomes are not met, the manufacturer pays back a predetermined sum or percentage. This may be per-patient or aggregate. E.g., "for each patient who fails to qualify, the manufacturer provides an X% rebate on that claim."
- **Tiered Pricing:** Payment per patient might vary by outcome achieved: full price if outcome hit, reduced price otherwise.
- **Aggregate Adjustments:** An overall performance guarantee, such as "if fewer than Y% of patients reach outcome, payers receive a lump-sum rebate."

Some contracts also include provisions for overachievement: if outcomes exceed targets, the payer might pay slightly more (though this is rare in practice, as payers prefer upside protection rather than upside for manufacturers).

Other financial terms might involve **caps and floors**: e.g. the manufacturer guarantees that, at worst, net price will not fall below a floor given typical results. The Velcade UK deal is effectively a floor: J&J gave up total revenue if outcomes were zero, preserving the NHS from paying high prices for no benefit (www.ajmc.com).

Internationally, some outcomes contracts are underwritten like insurance. For example, a manufacturer might purchase a separate insurance policy to cover claims if outcomes fail, rather than self-insure. There are even talks of "value bonds" or special contingency funds in the payer community.

Data Collection and Measurement

A critical implementation issue is **data infrastructure**. Outcomes-based contracts rely on capturing real-world data on prescribing, clinical results, and often patient characteristics. However, pharmacy claims alone usually lack clinical detail. At minimum, payers must obtain lab results, imaging or hospitalization records to validate whether targets are met (www.pharmexec.com) (www.pharmacytimes.com).

For integrated delivery networks (like Kaiser, VA), such data may exist in linked electronic health records (EHR). But for most payers or PBMs, data are siloed: pharmacy claims are separate from medical claims, and neither may fully capture lab values. Consequently, many contracts (especially earlier ones) used proxy outcomes that could be tracked via claims (e.g. fracture occurrence, hospitalization code) or those requiring manual reporting. The contract often specifies an independent third party (university or data analytics firm) to review results, enhancing credibility (www.pharmexec.com).

Example: Diabetes Drug Contract Data Needs

In the Cigna-Merck sitagliptin deal, measuring A1c reduction required access to patients' lab records. Cigna had to gather A1c values for members, likely via health plan data exchanging with providers or internal labs. They also tracked medication adherence via prescription refill data. These data then determined the rebate owed. Notably, Cigna reported success: A1c improved and testing rates rose (www.ajmc.com). But not all plans have this sophistication, which promised to limit replication.

Regulatory Considerations

U.S. federal law historically complicated VBC. Medicaid's Best Price rule required manufacturers to report their lowest price to Medicaid, which for many arrangements would be the discounted price after rebates. Thus, if a manufacturer gave payers a higher rebate under a VBC, Medicaid's share of rebates could inadvertently increase, a disincentive for states and companies to try outcomes deals. Recognizing this barrier, CMS proposed (and later finalized) safe harbors in 2020 to allow manufacturers to offer value-based contracts without triggering adverse best-price adjustments (www.cms.gov) (www.cms.gov). The proposal aimed to "modernize" reporting rules so that Medicaid (and by extension, Medicare Part D) would not get penalized when outcomes rebates were granted to other plans (www.cms.gov). In practice, these regulatory changes opened the door for more public-sector VBC, though details continue to evolve under different administrations.

Other legal aspects include anti-kickback and fraud laws: manufacturers and payers must ensure that rebates or price adjustments under VBC contracts are structured as permissible "discounts" rather than unlawful payments to induce prescribing. The Medicare Anti-Kickback Statute has safe harbors for discounts/rebates if properly documented, and most payers coordinate with counsel to fit into those frameworks (www.ajmc.com).

Technical and Administrative Infrastructure

On the operational side, contracts often require investing in IT and analytic capabilities. Pharma companies may help build or fund data collection tools to demonstrate outcomes, as suggested by some experts (www.pharmexec.com). Figure 3 (from Dean Erhardt, Contract Pharma) outlines levels of sophistication in collating data across payers, labs, and EHRs. Artificial intelligence and cloud-based real-time analytics are emerging as solutions to handle the volume and velocity of data needed (www.pharmacytimes.com) (link.springer.com). For example, new platforms promise to integrate pharmacy claims with lab feeds in near real time, allowing performance measurement continuously rather than retroactively.

Nevertheless, building such systems is costly and time-consuming. Many value-based programs today operate on a **retrospective** basis: data are collected over months or years, then analyzed and reconciled, and rebates calculated after the fact (www.pharmacytimes.com) (www.pharmexec.com). This retrospective model delays financial settlements and limits on-the-ground learning. The pharmacy expert article highlights the desire to move toward *continuous* value-based contracts, yet acknowledges that to date most VBC arrangement have been "retrospective analytic and reporting" processes (www.pharmacytimes.com).

Given these hurdles, some early adopters set low bars: focusing on one metric, excluding complex cases, or only applying VBC to specific subprograms. As industry voices note, scalability is a concern: it may not be feasible to have hundreds of tiny value-contract pilots for different drugs and payers. A consolidated effort, possibly through industry standards or shared registries, might help. For example, the Oncology Care Model (OCM, a CMS pilot) collected chemotherapy and care quality data from participating practices; similar registries could theoretically track drug outcomes for VBC. Efforts like these (e.g. HCPLAN's framework for value contracts [1†L169-L178]) indicate movement toward frameworks for continuity.

Stakeholder Perspectives

Value-based drug contracts implicate multiple stakeholders, each with distinct incentives, concerns, and roles. Understanding their views is crucial for analyzing the feasibility and design of VBC.

Pharmaceutical Manufacturers

Opportunities. From the industry side, VBC can offer a competitive strategy. By guaranteeing outcomes, manufacturers can justify premium launch prices and potentially secure market access that might otherwise be blocked by payers. As Novartis CEO Joseph Jimenez stated, they want to be "rewarded for the tangible outcomes [our products] provide" rather than just pill volume (www.pharmacytimes.com). If successful, manufacturers gain broader formulary

placement and differentiation (especially for “me-too” products in crowded classes). Outcomes contracts can also safeguard brand perception: offering a refund can signal confidence in the drug’s effectiveness.

Manufacturers acting as “solution providers” can build long-term payer relationships. For example, a firm that helps underwrite risk or provide data analytics may become a preferred vendor, smoothing network inclusion. The pharmaceutical executive quoted by PharmExec argued that companies must shift from a “price-per-pill” mindset to one based on patient outcomes (www.pharmexec.com). Thus, VBC is seen by some pharma leaders as the future path that aligns with the global push for value demonstration (Health Technology Assessment, patient-centered trials, etc.).

Risks and Costs. However, manufacturers also bear significant risk. Outcomes deals effectively cap or reduce the expected revenue if the drug underperforms. Companies must hold reserves or reinsurance for potential refunds, impacting cash flow. They also face information asymmetry: they may not easily know which specific patients failed, making it hard to track, and uncertain about external factors (e.g. patient behavior) affecting results. Transaction costs are high – developing models, negotiating terms, and managing data require resources. In the PharmExec article, authors note that evaluating contracts requires actuarial modeling of risk, using historical data on incidence, prevalence, and usage (www.pharmexec.com). Many pharma companies simply lack this internal capability, and not all want to invest unless the potential payoff (market access/profits) is certain.

Moreover, manufacturers worry about precedent. If one contract sets a particular outcome threshold, others may demand similar terms. Guaranteeing outcomes on one product invites scrutiny on pipeline. There is also concern over “indication creep”: if a drug later gets new indications or combos, prior guarantee obligations might be strained. Legal considerations about anti-kickback/REBATE rules further complicate contracts. Historically, some companies have balked at VBC, preferring to keep price lists stable and use rebates in the traditional way.

Payers (Insurance Plans, Medicaid, Providers)

Payers’ motivations. Payers seek to control spending and ensure patients get effective treatments. A well-designed VBC can prevent wasted spend on failed therapies: if an expensive drug doesn’t work, they recoup costs. VBC can also focus attention on outcomes tracking, potentially improving care management. For employers or insurers, being able to say “we only paid full price for drugs that helped” has PR value. Some large plans have small but growing VBC portfolios as pilots for high-spend categories (e.g., CVS’s $10B specialty drug portfolio could launch dozens of such trials). Government payers (Medicaid, Medicare) see VBC as aligning with public interest in prudent use of funds.

Challenges (Payers). Payers face hurdles similar to manufacturers: data tracking and administrative overhead. Many payers report that the negotiation and monitoring costs may

exceed the gains. ContractPharma cites payer concerns that rebates from unmet outcomes might not offset the investment needed to build analytics (www.contractpharma.com). Indeed, some payers have had minimal "meaningful rebate differences" despite setting up deals, raising questions about net savings (www.contractpharma.com). Bias can also occur: a payer negotiating may fear that pharma sets targets too easily or in metrics not correlated with genuine benefit. Concerns about transparency and confidentiality (discussed below) also affect payers' willingness to engage publicly.

A particular issue for public payers is legislative constraints. While CMS's 2020 safe-harbor rule eased Medicaid best-price issues, Medicaid managed care plans and Medicare still have limited legal authority compared to fully private sectors. Some large employers or health systems have more flexibility. In the U.S., for example, only certain Medicare Advantage plans can try novel deals (Part D is more complicated). By contrast, European single-payer systems often dictate terms. That difference partly explains why many early VBC innovations emerged in Europe or with large integrated systems, and U.S. private payers have been slower to rollout deals broadly (www.pharmexec.com) (www.mckinsey.com).

Patients and Providers

Patients are indirect stakeholders. Ideally, outcomes contracts improve patient care by encouraging adherence support and monitoring. Some contracts require manufacturers to fund patient education or disease management programs as part of partnership with payers. In the PharmacyTimes articles, specialty pharmacies are positioned as trusted agents to improve adherence curbing waste (www.pharmacytimes.com) (www.pharmacytimes.com). If VBC leads to insurers covering high-cost therapy that might otherwise be denied, patients benefit. However, many experts caution that these deals do *not* directly lower patient out-of-pocket costs. For instance, ContractPharma notes that rebates from outcomes contracts typically flow to payers retroactively, not to patients at the pharmacy counter, so coinsurance remains high (www.contractpharma.com). There is recognition that future policy adjustments may be needed so that patients share savings (e.g., lower premiums or copays in exchange for VBC savings) (www.contractpharma.com).

Providers (physicians, hospitals) are largely bystanders: physician payments remain separate. However, providers do play a role as data sources (reporting outcomes) and must coordinate care. If providers know a patient is in an outcomes-contract, they may be more diligent in follow-up (since the payer and manufacturer have a stake in the outcome). Conversely, if the contract is purely administrative between payer and manufacturer, providers may see little benefit or burden, as one article noted: they have enough to manage without dealing with formulary politics or extra forms (www.pharmacytimes.com).

Health Technology Assessment (HTA) Bodies and Regulators

In publicly financed systems, HTA bodies like NICE in the UK or IQWiG in Germany increasingly influence pricing frameworks. These organizations have traditionally used cost-effectiveness thresholds to negotiate price, but they have also engaged in performance-based deals. For example, NICE's deal for Velcade effectively allowed market access subject to proven on-going value (www.ajmc.com). Some argue VBCs should be seen as complements or alternatives to rigid HTA thresholds. However, HTA analysts caution that performance contracts are hard to monitor and enforce at population scale. The French system, for instance, imposes outcomes stipulations or rebates for many new drugs (often confidential), but the lack of transparency and complexity has drawn criticism.

In the U.S., government regulators (FDA/CMS) do not directly set prices, but they influence the landscape. FDA accelerated approvals (based on surrogate endpoints) can create disconnects: a drug might appear effective on a biomarker, but real-world benefits are uncertain. This drives interest from Medicaid programs to use VBC as a way to hedge the risk of uncertainty. CMS support (as per 2020 rule) indicates federal encouragement, but actual regulatory guidance (especially under new administrations) remains in flux. In short, value-based contracts are overseen by existing payment and antitrust regulators rather than a special VBC regulator.

Pharmaceutical Benefit Managers (PBMs) and Distributors

PBMs, which negotiate on behalf of insurers and pass drugs at pharmacies, are gradually entering the VBC arena. Large PBMs have started to commission deals (e.g. CVS Caremark's collaboration with manufacturers for rebates on outcomes, though details are often confidential). PBMs claim VBC can be another tool in formulary management, but many have not published specifics. Their challenge mirrors insurers: aligning pharmacy data with medical outcomes is resource-intensive. Some PBMs partner with data analytics firms to track metrics. The PharmacyTimes series notes that specialty pharmacies, often under PBMs or integrated health systems, might act as neutral intermediaries to adjudicate contracts (www.pharmacytimes.com) (www.pharmacytimes.com).

Distributors (wholesale) and pharmacies themselves are generally indifferent to the pricing model, as reimbursement flows through payers/pharmacists as usual. Their role may be limited to providing adherence support services.

Empirical Evidence and Data

Prevalence of Value-Based Contracts

Despite decades of discussion, outcomes-based contracts remain relatively uncommon in practice. Public data are scarce because most deals are confidential. However, analyses of disclosed arrangements give an indication:

- **Global Number of Deals:** A 2017 McKinsey survey identified over 200 publicly disclosed innovative arrangements worldwide since 1994, of which about 50 were U.S.-based (www.mckinsey.com). (Note: "innovative" here includes various schemes, but a significant share were outcomes-based). Roughly half of these disclosed contracts were in oncology, with the rest mostly in rheumatology, cardiology, endocrinology, etc (www.mckinsey.com). Europe (especially Italy, Spain, France) led early development (www.mckinsey.com). Italy alone accounted for ~35% of these deals, largely due to mandates for outcomes contracts in certain drug classes (www.mckinsey.com). The U.S. only saw a burst of contracts after 2014, with maybe 4 deals that year and up to 8 by 2017 (www.mckinsey.com).

- **US Market Trends:** Within the U.S., industry surveys (e.g. by CPMA/Prime Therapeutics) indicate that as of 2019, more than half of health plans had experimented with at least one outcomes-based contract (www.hmpgloballearningnetwork.com). However, the majority of these plans still put only a small fraction of their formulary on VBC terms. The ContractPharma article (2019) reports many plans negotiating "meaningful" rebates under such deals, but cautions that limited metrics and applicability hinder broad savings (www.contractpharma.com). According to HCP-LAN (Health Care Payment Learning & Action Network), roughly 40% of U.S. healthcare payments remain fee-for-service (Category 1), implying that even after a push to value, outcomes contracts are still niche. An often-cited HCP-LAN estimate (pre-2020) projected potentially 100% of care could be value-based by 2025, but in practice most VC has focused on provider payments rather than drug pricing (www.intechopen.com).

- **By Therapy Area:** Value-based arrangements have clustered in certain areas. Specialty biologics for chronic conditions or new curative therapies tend to attract VBC. Examples include diabetes drugs (Januvia pact with Cigna), PCSK9 cholesterol drugs (Amgen Repatha had several outcomes contracts), autoimmune medications (Amgen's Enbrel deals in multiple countries), and hepatitis C antivirals (several state Medicaid contracts). Oncology is a major focus, with multiple deals for CAR-T cells, immunotherapies, and targeted agents. Respiratory (e.g. inhalers) has seen some exploration (e.g., $/avoid hospitalization), as have rare disease meds (e.g. Fabry disease enzyme replacement). In general, the pattern is: high-cost drug + measurable outcome + potential for uncertainty = candidate for VBC (www.mckinsey.com) (www.mckinsey.com).

- **Savings and Spend:** Quantitative data on savings are hard to come by. Select contracts have yielded reported benefits: e.g. one osteoporosis deal (Actonel, 2009) reportedly saved the insurer 79% less than the cap (www.ajmc.com). Washington state projected 40% per-patient cost drop using a subscription model for hepatitis C (www.fiercepharma.com). However, comprehensive studies are lacking. The Kesselheim et al. (J Gen Intern Med 2017) systematic assessment of outcomes contracts found "no evidence" that any implemented contract reduced total spending or improved outcomes yet (pubmed.ncbi.nlm.nih.gov). The ContractPharma analysis also cautions that on a broad scale, outcomes contracts "are not likely to lower spending," at least in the near term (www.contractpharma.com), due to their narrow focus and limited metrics.

Barriers to Adoption

Several analyses have enumerated barriers, which help explain low prevalence:

- **Contract Complexity and Costs:** Both industry and academic sources emphasize that negotiating and administering each VBC is significantly more complex than a standard rebate contract (www.pharmexec.com) (www.contractpharma.com). Payers cite the need for specialized actuarial analysis to design the contract, higher legal fees, and longer negotiation timelines (www.pharmexec.com) (www.pharmexec.com). Many payers and manufacturers have limited resources or experience for this. A survey highlighted that annual workload (employer contracts plus disease management) and doubts about net savings slowed adoption (www.contractpharma.com).

- **Data and Infrastructure:** As noted, lacking up-to-date clinical data hinders measurement. The need to set up or access registries or EHR data is nontrivial. For example, a European review notes that tracking outcomes across institutions (especially in fragmented systems) is a major obstacle (www.pharmexec.com). Privacy regulations (HIPAA) add friction to sharing patient-level info between payer and manufacturer. This "fragmentation of data" often means payers rely on coarse measures or partner with specialty pharmacies to gather information (www.pharmacytimes.com) (www.pharmacytimes.com).

- **Patient Mobility:** In markets like the U.S., patients frequently change insurers yearly. A big risk is "churn": a payer might pay a floor price for a therapy it hopes will pan out over 3 years, but the patient could move to a new insurer before results appear. Then the paying plan shoulders the cost but leaves before capturing all the upside (or offsets). This makes payers hesitant to commit to long-term deals unless arrangements follow the patient or are backstopped (a concept in industry discussion about portable warranties (www.pharmacytimes.com)).

- **Measurement Challenges:** Choosing and agreeing on outcomes is itself difficult. The AJMC article noted that "few companies will want outcomes contracts if the measure of success goes past the drug monotherapy" (www.ajmc.com). Both parties must agree on what constitutes success (biomarker target, time frame, etc.), and ensure it is clinically appropriate. Misaligned incentives (manufacturer might favor eas [y] endpoints, payer wants hard outcomes) complicate negotiations.

- **Legal/Regulatory Uncertainty:** While some regulations have been loosened, uncertainty remains. Drug companies worry about how outcomes rebates affect international reference pricing (other countries referencing U.S. list price, etc.). Payers worry about anti-kickback/False Claims rules if structure is unclear. This caution delays deals.

In sum, the literature agrees that VBC, though growing, is still small-scale. Analysts caution that, practically speaking, these contracts have "not lived up to potential" yet (pubmed.ncbi.nlm.nih.gov) (www.pharmexec.com). The conditions for success appear strict: products with clearly defined patient populations, measurable short-term outcomes, and partners with data/motivation are prime candidates (www.mckinsey.com) (www.mckinsey.com). Going forward, building case examples and better infrastructure is seen as crucial to scaling up.

Case Studies and Examples

To ground the discussion, we examine specific examples of value-based contracts (both programmatic and drug-specific). These illustrate how VBC is applied in reality, and what outcomes emerged.

1. Johnson & Johnson – Velcade (Bortezomib) – UK NHS (2007)

Context: Velcade (bortezomib) is a proteasome inhibitor used for multiple myeloma. In 2007, NICE (UK HTA body) initially deemed Velcade not cost-effective for routine use. To gain access, J&J negotiated a conditional deal with the National Health Service (NHS).

Contract Term: J&J agreed that Velcade use would require a "50/50" guarantee: For each patient treated, if after 4 cycles of therapy the level of paraprotein (M-protein, a disease marker) had **not** fallen by at least 50%, J&J would reimburse the NHS the full cost of that patient's Velcade treatment (www.ajmc.com). In practice, reimbursement typically took the form of supplying additional free doses (i.e. continuing therapy at company cost until response achieved).

Outcome: This contract effectively served as an individual performance guarantee. Patients who responded continued therapy at no NHS cost, while non-responders cost the manufacturer. The deal made Velcade essentially free for patients verifying non-response. NICE agreed to this arrangement and covered Velcade under these conditions, and J&J was able to sell the drug. This was one of the first explicit outcomes-based pharma contracts, often cited as a prototype (www.ajmc.com). It showed that payers could shift principal risk (lack of efficacy) to manufacturers. Though internal NHS data on overall impact were not public, the arrangement allowed many patients access to Velcade who otherwise wouldn't have received it.

2. Merck – Sitagliptin (Januvia) – Cigna (2009)

Context: Sitagliptin (alone or combined with metformin) is a DPP-4 inhibitor for type 2 diabetes. In 2009, one of the first U.S. payer-manufacturer VBCs was announced: Cigna (national insurer) and Merck.

Contract Term: Under the deal, Merck provided two levels of additional discounts. First, if a patient on sitagliptin achieved a certain reduction in HbA1c (a glycemic control measure), Merck gave a rebate. Second, if the patient demonstrated adequate adherence to the medication (i.e. took it as prescribed), Merck gave an additional rebate (www.ajmc.com). In return, Cigna placed these drugs on a low copay tier to encourage patients to enroll in the program.

Outcome: Cigna reported that the program led to a >5% average improvement in blood sugar among continuously enrolled members on the drugs, and a 4.5% increase in frequency of HbA1c

testing (www.ajmc.com). These gains suggest both better adherence and monitoring, though it's unclear how much was directly attributable to the contract incentives versus other factors. Merck did have to pay some rebates, but the program was said to help confirm the real-world effectiveness of sitagliptin.

Significance: This case is often cited because it was transparently announced (press release) and showed feasibility on a large scale (Cigna had millions on its plans). It combined clinical metrics (HbA1c) with behavioral (adherence). However, it was also unusual in offering two-tier rebates and required careful patient engagement. Studies did not show massive cost savings, but it created a precedent in the U.S. for diabetes outcomes contracts.

3. Osteoporosis Drugs – Health Alliance Plan (HAP) – Procter & Gamble/Sanofi (2009)

Context: In 2009, the Health Alliance Plan (a Michigan health maintenance organization) contracted with Procter & Gamble and sanofi-aventis around risedronate (Actonel) for osteoporosis. At the time, questions about the real-world efficacy of bisphosphonates (to prevent fractures) had made payers cautious.

Contract Term: The insurers and manufacturers agreed that if any eligible woman on Actonel suffered a **non-spinal osteoporotic fracture** during a specified period, the manufacturers would reimburse HAP for the treatment costs of that fracture, up to a set financial limit (www.ajmc.com). Essentially, the burden of fracture risk was shifted to the companies: they took on the cost of failure (fractures represent failure of drug to prevent events).

Outcome: After 9 months, the program found that actual fracture-related payouts by the manufacturers were **79% lower** than the pre-set maximum liability (www.ajmc.com). In other words, fewer women fractured than expected from historical data, so HAP saved money (keeping Actonel on formulary delayed considering switching to alternatives). The real-world fracture rate appeared low. From Procter & Gamble's standpoint, the low payout (they paid only 21% of worst-case) validated that Actonel's trial-proven efficacy held up in practice (www.ajmc.com).

Significance: This contract is notable as a financial risk-sharing rather than an outcomes guarantee to patients. It assured the health plan that drug coverage wouldn't cause runaway fracture costs, and it provided payers with data on effectiveness (since reimbursed fractures were carefully tracked). It also few gave Brittle outcome. It suggests that, at least for this case, VBC served more as utilization and safety net than as a major cost driver – the manufacturers did not have to pay much (presumably making it a manageable risk for them).

4. Italian and Other European Schemes

Europe has seen many confidential risk-sharing agreements, often mandated by law. Italy in particular requires performance-based agreements for certain new drugs. Reports indicate dozens of such contracts for cancer and rare disease drugs. Unlike the above, most Italian deals are not publicly profiled. However, they typically involve "pay for non-response": if a patient does not respond within a time period, the company refunds the cost of that patient's treatment. The McKinsey findings noted Italy alone had about 35% of all disclosed innovative deals globally, largely through such agreements (www.mckinsey.com).

In Spain's Catalonia region, at least seven outcomes contracts (versus two in other regions) were implemented by 2017. CatSalut reportedly developed IT tools and unique patient IDs to track these agreements (www.mckinsey.com). Similarly, in France, the government sometimes requires deferred payment or refunds on epilepsy or cancer drugs if patients stop treatment. These illustrate that in single-payer systems, policymakers can enforce more uniform VBC than fragmented insures in the U.S.

5. Hepatitis C Subscription Models (Louisiana & Washington, 2019–2020)

Context: The newest wave of VBC-like arrangements involves the "subscription" model for hepatitis C virus (HCV) cures. Two U.S. states made headlines: Louisiana (2019) and Washington (2020). These are often called "Netflix" models.

Contract Terms (Louisiana): The state Medicaid ($, managed by Louisiana Health Dept) entered a 5-year agreement (2019–2024) with Asegua (subsidiary of Gilead) for unlimited access to the HCV drug Epclusa. For a fixed fee of about $58 million per year (total $290M), Gilead agreed to supply as many courses of therapy as needed for Medicaid and prison populations (www.fiercepharma.com). The contract effectively lowered the price per patient (est. $10k each vs $80k list price).

Contract Terms (Washington): Similarly, Washington state negotiated with AbbVie end-to-end for its drug Mavyret (followup to Gilead's drugs). Washington agreed to pay roughly the same annual budget (~$80M) but expected to double the number of treated patients (roughly 30,000 over 4 years) with AbbVie supporting patient outreach, (www.fiercepharma.com) (www.fiercepharma.com). Specific performance metrics were state projections (treating half of all eligible HCV patients) and reducing per-person costs by ~40%.

Outcome / Early Results: These contracts focus on broad access rather than individual outcomes. Early reports (late 2019–2021) indicate the state programs are achieving higher treatment volume and lower per-patient cost. For example, Washington's program aimed to erase 65,000 HCV cases; by 2021, spending roughly the same as before but for ~30,000 patients (www.fiercepharma.com). Louisiana's deal targeted all 39,000 Medicaid/prisoners with

HCV. These arrangements essentially bank on volume discounts and public health benefits of curing disease.

Significance: Though not tied to clinical outcomes per patient, these state contracts are drawn into VBC discussion because of their innovative structure and focus on value (curing a disease at scale). They demonstrate how public purchasers can use guaranteed budgets to advance population health goals in exchange for lower unit costs (www.fiercepharma.com) (www.fiercepharma.com). They also underline potential drawbacks: contract details remain partly secret (so metrics aren't fully public), and state reforms were needed (limiting to Medicaid and corrections populations) to sidestep Medicaid best-price rules originally.

6. Various Private and Public Contracts

Other examples include:

- **Amgen Repatha (evolocumab, PCSK9 inhibitor):** Amgen announced 2015-2017 several outcomes programs with US payers on Repatha. Some tied rebates to LDL-cholesterol lowering or heart attack outcomes. A notable one was the New York Cardiovascular Health Study: if Repatha did not reduce major cardiovascular events as projected, Amgen would reimburse. However, results of these programs have not been fully disclosed; some reports in 2018 suggested poor adherence to injection therapy and amendments to contracts. Likewise, Sanofi/Regeneron had a similar scheme for Praluent (their PCSK9). A paper published after the FOURIER trial (which showed lower-than-expected benefits for Repatha) noted that actual outcomes fell short of modeled targets (www.drugpricinglab.org), implying that payers benefited from Amgen's guarantee.
- **Merck Januvia (sitagliptin) – Aetna (2016):** Merck struck a VBC with Aetna for Januvia in diabetes, similar to the Cigna deal, rewarding glucose control (www.mckinsey.com).
- **Novartis Kymriah (CAR-T therapy):** Novartis offered payments contingent on patient response at 1 month; unclear if any rebate occurred.
- **Spark/Roche Luxturna (gene therapy for retinal disease):** Launched at $425,000/eye, Spark offered outcome-based payments to insurers (years) if patients lost vision outcomes, but details and uptake were murky. Some state Medicaid and commercial insurers put caps or staged payments.
- **AbbVie Humira and other blockbusters:** Some European countries (like Netherlands) have discussed pay-for-performance for top sellers, though most deals seem exploratory at industry events (not publicly reported).
- **Subscription for other cures:** For example, states are exploring "outcomes funds" where insurers contribute to a fund that would reimburse failures.

Given the rapid pace of this field, many pilots exist that may not yet be published. Table 2 (next page) lists selected known contracts.

Year	Company	Drug (Indication)	Payer/Country	Outcome Metric	Contract Key Terms/Results
2007	J&J	Velcade (myeloma)	UK NHS	≥50% reduction in M-protein by 4th therapy cycle	If failed to achieve reduction, J&J reimbursed full cost (via free drug). Enabled NHS coverage (www.ajmc.com).
2009	Merck	Januvia/Sitagliptin (diabetes)	Cigna (USA)	HbA1c reduction & adherence rates	Merck gave rebates if patients met A1c targets and adhered; Cigna put drug on low copay tier (www.ajmc.com).
2009	P&G / Sanofi-aventis	Actonel (osteoporosis)	HAP (USA)	Non-spinal fracture occurrence	Manufacturers reimbursed treatment cost for fractures; actual reimbursements were 79% less than liability cap (www.ajmc.com).
2014	Novartis	Lucentis (AMD)	NHS England (UK)	Injections beyond 14 per patient	Novartis covered cost of injections beyond dose cap of 14 (as recommended by NICE) (www.mckinsey.com).
2015	Eli Lilly	Forteo (osteoporosis)	Harvard Pilgrim (US)	(Not public)	Seletive outcomes deal reportedly to add Forteo to formulary; likely pay for patient-level outcomes (www.mckinsey.com).
2017	Cigna	Harvoni (HCV, ledipasvir)	Cigna (US)	Sustained virologic response (SVR)	Cigna's deal for Harvoni (~$90K) tied to cure rate; details undisclosed (www.mckinsey.com).
2017	Amgen	Enbrel (rheumatology)	Various (AUS, Canada, US)	(unspecified)	Outcomes-based contracts to address competition/biosimilars (e.g. outcomes guarantee) (www.mckinsey.com).
2018	AstraZeneca	Brilinta (ticagrelor, cardiology)	Harvard Pilgrim (US)	Hospital readmission rates	Measured effect on cardiovascular readmissions among treated acute coronary disease patients (www.mckinsey.com).
2019	Gilead/AbbVie (tbd)	Mavyret/Epclusa (HCV)	Washington/LA Medicaid	Population-level cure rates	"Netflix" subscription model: fixed fee for unlimited treatments. Washington: $80M/year for ~30,000 patients (www.fiercepharma.com) (www.fiercepharma.com).
2020	Spark Therapeutics	Luxturna (gene therapy, blindness)	Various (US)	Vision response	Spark reportedly offered outcomes-based payment if visual improvements were not sustained at 30 days (details opaque).

Table 2: Selected outcomes- and performance-based pharmaceutical contracts (non-exhaustive).

These cases highlight the variety of structures and challenges. Some contracts (Velcade, diabetes) had clear, objective measures and reported successes. Others (e.g. many EMR deals) remain confidential or poorly documented. The hepatitis C subscription model is distinct: instead of per-patient metrics, it measures population impact (treatment volume and long-term savings). It blurs the line between outcomes and financial risk-sharing.

Discussion: Impacts and Debates

The use of VBC raises a number of broader questions about value in healthcare, innovation incentives, and system costs. Below we discuss key themes from research and expert commentary.

Do Outcomes Contracts Improve Value or Lower Costs?

The central promise of outcomes-based contracts is that they will align spending with efficacy. On a per-patient basis, one would think that shifting financial risk to the manufacturer should avoid paying full price for poor responders. **However, real-world evidence for cost savings is limited.** A qualitative study by Kesselheim et al. (2017) involving stakeholders found that, while interest is high, "the power of these contracts to curb spending is questionable" (pubmed.ncbi.nlm.nih.gov). Because VBCs have only been applied to a narrow drug subset (expensive, measurable-outcome drugs), their impact on total drug spending is minimal. Payers still pay fixed (often high) list prices for the vast majority of prescriptions. ContractPharma concurs, noting that outcomes contracts "could potentially move spending toward more effective treatments, but they are not likely to lower spending on a broad scale" (www.contractpharma.com). The Commonwealth Fund (cited in ContractPharma) estimates these deals will remain limited in scope and uses mostly proxy measures not directly tied to major health gains.

Critics also argue that manufacturers can game the system by raising list prices to anticipate rebates. Because rebates under VBCs apply retroactively, companies may initially increase the price knowing they will refund part anyway, thus shifting costs to patients (who pay coinsurance on list price) and to other payers. ContractPharma explicitly warns that pharma could raise initial prices to preempt the impact of expected rebates (www.contractpharma.com). Furthermore, since patient copays occur at OOP before rebates, patients see no immediate savings from such deals (www.contractpharma.com).

From a value standpoint, if outcomes are truly achieved, then by definition the drug is valuable and worth its price snippet. But if outcomes are only marginally better than standard care, the incremental value might not justify the premium price – and an outcome-based rebate doesn't change the fundamental price-volume calculus. In summary, on the narrow contract scope, both sides can benefit (manufacturers secure the sale; payers recoup some refunds), but the net effect on overall health spending is uncertain.

Impact on Access to Innovation

Proponents claim that VBCs can improve patient access to novel therapies. By removing uncertainty, payers might cover drugs they otherwise would exclude. For example, if a cure has an uncertain success rate, a contract could reassure payers. In mental health analogies, it's "guarantee or no guilt." Novartis's Jimenez envisions that collaboration on reimbursement can

"help start a shift toward value pricing" (www.pharmacytimes.com), implying greater market uptake for truly effective products. However, it remains an open question whether VBCs have meaningfully expanded access so far. In many cases where contracts have been tried, the drug might have been covered anyway with prior authorizations. For instance, Cigna covered Januvia even before the Merck deal; the contract just gave additional rebates. Velcade's UK deal arguably did expand access, since NICE had initially not recommended it. On the other hand, some deals have been seen as "pay-to-play" where the therapy is already indicated, and the deal is more about financial protections than new access.

It's also important to consider equity: if VBCs lead payers to cover only those patients on whom outcomes were guaranteed, it could paradoxically limit access (e.g., if contracts define narrow inclusion criteria, others might face denials). Moreover, vulnerable patient groups, who often have less reliable follow-up and lower adherence, could be disadvantaged under outcome-based reimbursement frameworks.

Effect on Clinical Practice and RWE Generation

An optimistic view is that outcomes contracts force measurement of real-world effectiveness, generating data that can improve care. For example, the diabetes contract reportedly increased rates of HbA1c testing by 4.5% (www.ajmc.com) – broadly beneficial. Payers and manufacturers might jointly invest in RWE studies, registries, or patient tracking. Such data could inform future guidelines or help refine predictive biomarkers. Intermediate results from some German and Italian contracts have fed into national cost-effectiveness assessments.

However, skepticism exists about how robustly outcomes data will be collected. If contracts rely on "billing proxies" (e.g. hospital admissions coded in claims) rather than granular clinical measures, the feedback to care is weak. Also, industry critics note that many value outcomes are publicly inaccessible (contracts are secret), limiting scientific appraisal. The FiercePharma article on hepatitis C highlights transparency issues: terms of state deals remain hidden under trade secret laws (www.fiercepharma.com), meaning we don't know how success is truly measured or if savings occur as promised.

Alignment of Incentives

A recurring theme is misalignment of what constitutes "value." Patients might value symptom relief and quality-of-life; payers value cost offsets, and regulators value broad population health metrics. One researcher observed that "the biopharma's challenge is that the term 'value' might mean different things to different stakeholders" (www.researchgate.net). For example, a therapy that significantly eases chronic pain might not reduce costs promptly, so payers may not favor it under a VBC framework. Conversely, life-saving therapies might justify large payments even if quality-of-life gains are marginal.

There's also a risk that focusing on one metric can distort behavior. If reimbursement depends on short-term lab targets, providers might "treat to the test" or postpone therapy for borderline cases. Good contract design tries to mitigate gaming (e.g. requiring baseline measurements, independent audits, risk adjustment), but it's inherently complex.

Theoretical Economic Perspective

Economists studying healthcare markets note that VBC can, in theory, lead to more efficient allocation if done correctly, by internalizing post-market performance risk. Yet, they also warn about unintended effects. For instance, if manufacturers offer rebates only for the approved indication, payers might push patients toward use-case where a refund exists and away from off-label or untested uses – potentially stifling some off-label innovation. Alternatively, complex pricing contracts can reduce transparency, leading to price dispersion and making international referencing more difficult.

The "willingness vs ability" to implement value agreements has been codified in frameworks (Gary Branning et al.) noting that even if desired, the practical ability (data, legal, etc.) often lags (www.ajmc.com). Some scholars argue that outcomes contracts are rarely Pareto-improving (benefiting both sides) unless truly structured with full information.

In summary, the consensus from literature is guarded optimism: value contracts might *encourage* efficient outcomes if aligned properly, but they are no panacea. They should be one of many tools (alongside HTA, formularies, competition) in the broader effort toward cost-effective care (pubmed.ncbi.nlm.nih.gov) (www.researchgate.net).

Challenges and Barriers

We have already alluded to many practical barriers. Here we explicitly detail major categories:

- **Data and Measurement:** Capturing outcome data at scale is perhaps the single largest hurdle. A healthcare executive quoted by *Pharmacy Times* observed that shifting to real-time monitoring versus retrospective analysis is a critical leap and not yet fully realized (www.pharmacytimes.com). The need for interoperability across EHRs, claims systems, and labs – and the lag in legislative data-sharing reforms – means most current VBC metrics are cobbled together from imperfect sources. Outcomes themselves can be ill-defined: if a diabetic's A1c falls by 0.4% rather than 0.5%, does that trigger a partial rebate? Contracts often oversimplify into binary successes.

- **Population Turnover:** The issue of patient churn undermines risk alignment. Without mechanisms to track a patient beyond the current payer, one cannot guarantee payers are the only ones to benefit (or suffer). Some proposals address this, such as glue agreements between payers, or annuities spread across future insurers, but these are complex. Currently, many deals ignore churn, meaning they are better suited to closed systems (e.g. national health services or large HMOs) than open commercial markets.

- **Financial and Administrative Costs:** Both payers and pharma incur higher administrative expenses for VBCs. Negotiations can be lengthy (often 6–12 months for one contract), involving legal teams, actuaries, and finance experts. Then the ongoing administration (tracking, auditing, reconciling payments) can require annual or quarterly effort. A small payoff (say a few million in rebates) may not justify multi-million-dollar ROI on implementation for either side. This reality has kept many deals in pilot phases or narrow scope.

- **Lack of Standards and Precedents:** Without industry standards, each contract is a unique negotiation. This hinders scaling: pharma cannot deploy a "template" value-contract for every country. The PharmExec authors advocate standardizing core contract structures to accelerate adoption (www.pharmexec.com). Similarly, payers may lack frameworks to evaluate potential agreements. Because there is little historical precedent to benchmark against, uncertainty is high for both sides.

- **Economic and Strategic Concerns:** Some payers are cynical, suspecting manufacturers won't enter fair contracts. Conversely, some manufacturers fear partners might game the system. If one party perceives the other as untrustworthy, negotiations stall. Academic commentators have warned that without trust or independent oversight, VBCs might transform into convoluted rebate swaps rather than genuine harm-reward mechanisms (www.pharmexec.com).

- **Regulatory and Policy Uncertainty:** The partial policy reforms (CMS 2020 rule) have helped, but broader Medicare and global policies could still impede. For example, changing U.S. drug pricing laws (e.g. proposals for more direct price controls) might make companies less willing to experiment with VBC if they believe a different policy approach threatens profits. Similarly, anti-corruption regulations in other countries might have nuanced impacts. The lack of clarity on how outcomes metrics factor into standard cost-effectiveness reviews can also be an impediment.

- **Metrics of Success:** There is as-yet no consensus on how to evaluate the success of VBC programs themselves. Is it the rebates collected? Health outcomes of covered populations? Cost savings? In academia, metrics like "value-based penetration" of contracts have been used, but no field-wide KPIs. This lack of evaluation makes it hard to refine or justify programs.

The culmination of these barriers means that many experts caution that outcomes-based contracting is not a quick fix. It will likely require iterative learning. Demonstration projects (like Medicare's Center for Medicare and Medicaid Innovation pilots) are recommended to gather evidence before large-scale rollout (www.contractpharma.com) (pubmed.ncbi.nlm.nih.gov).

Data Table: Operational Models

To summarize and contrast contract structures, Table 3 compares key features of outcomes-based pricing versus other models. This highlights the trade-offs in practice.

Feature	Outcomes-Based (Performance)	Financial Risk-based (Cap/Sub.)	Subscription/Netflix
Price Determination	Initially full price; manufacturers pay rebates if outcomes fail (www.contractpharma.com).	Price may include built-in risk (flat fee covers expected spend) (www.mckinsey.com).	One-time or periodic flat fee for broad access (price independent of units).

Feature	Outcomes-Based (Performance)	Financial Risk-based (Cap/Sub.)	Subscription/Netflix
Risk Sharing	Manufacturer assumes risk of clinical failure; payer assumes risk of unpredictability of response.	Pharma covers spending beyond cap; payer gives market exclusivity or guaranteed volume.	Pharma covers treatment costs beyond contract; payer has fixed budget risk.
Outcome Measurement	Requires individual patient data on specific clinical measures (e.g. lab values, preventable events) (www.ajmc.com).	Usually does not require outcome data; may track total spend or utilization.	Typically does not require outcome metrics (focuses on total population cures or volume) (www.fiercepharma.com).
Administrative Complexity	High: complex negotiation (metrics, definitions), data collection, auditing (www.pharmexec.com) (www.contractpharma.com).	Moderate: simpler to define (cap amount) but more actuarial analysis needed initially; moderate data (utilization) is needed.	Moderate: one time negotiation; requires verification of population size and eligibility, less granular data.
Examples	Velcade (UK) (www.ajmc.com), diabetes drug deals (Cigna–Merck) (www.ajmc.com), cancer therapy rebates.	Novartis Lucentis cap (UK) (www.mckinsey.com), budgets for eg. hepatitis C curative courses.	Louisiana/Gilead Hep C deal, Washington/AbbVie Hep C (Netflix model) (www.fiercepharma.com).
Advantages	Directly aligns payment with real-world efficacy; can encourage adherence/support programs; may improve access to high-value therapies.	Budget predictability; easier to administer than individual outcomes; protects against cost overruns without requiring clinical confirmations.	Guarantees broad treatment access; simplifies budgeting; focuses companies on volume goals and public health outcomes.
Challenges	Outcome definition disputes; data burden; patient eligibility ambiguity; potential for patient churn; uncertain savings.	May still pay high aggregate price despite poor individual outcomes; might under-incentivize achieving better results since insurer bears no performance obligation.	Ensuring only eligible population (risk of overtreatment?); companies may recoup cost via initial lump sum; less focus on *value* per patient.

Table 3: Comparison of value-based vs other innovative pricing models.

Future Directions

Looking ahead, value-based contracting in pharmaceuticals is poised to evolve. Several trends and research directions are noteworthy:

- **Learning from Early Pilots:** Initial contracts, even if limited, provide learning. Publication of success stories (like diabetes deals increasing adherence (www.ajmc.com)) and failures will inform more pragmatic approaches. Stakeholders have called for open evaluation, especially in public programs. For example, the Harvard study suggested piloting VBC in Medicare/Medicaid with rigorous academic oversight (pubmed.ncbi.nlm.nih.gov).

- **Data and Digital Health Advances:** Technological improvements will gradually reduce barriers. Interoperable EHRs, national health identifiers (as in Catalonia (www.mckinsey.com)), and standardized registries could make outcomes tracking easier. Artificial intelligence may help predict risk and analyze outcomes, as hinted by a recent J Pharm Policy Pract article on AI optimizing VBC evaluation (pubmed.ncbi.nlm.nih.gov). Blockchain solutions have also been suggested to securely share outcome data.

- **Payment Innovation for Gene and Cell Therapies:** The explosion of single-administration cures (gene therapies) has accelerated exploration of VBC variants like annuities (installment payments) and outcomes warranties (www.cms.gov) (link.springer.com). For example, CMS now considers permitting multi-year payments for high-cost cures if outcomes endure. Real-world data from early gene therapy outcomes (like durability in hemophilia or spinal muscular atrophy) will be critical; we expect more contracts coupling payment to long-term functional gains (link.springer.com). States and insurers are particularly motivated to apply VBC here due to big budget impacts.

- **Global Policy Shifts:** The U.S. political environment is mixed: while drug price debates continue, there is interest across parties in experimenting with VBC because it is seen as less heavy-handed than outright price controls. Europe and other regions (Australia's national curative CVD subscription, England's managed access agreements) will continue to refine their approaches. New international models may emerge, like cross-border outcomes studies or multilateral contracts.

- **Broader Value Frameworks:** The notion of "value" is broadening to include patient experience and societal value (e.g. rare disease treatments' broader impact). Future contracts might attempt to incorporate quality-of-life or societal outcomes (though measuring these is especially challenging in a contract context). There is also talk of bundling (e.g. paying for an episode of care including drugs and services) as a variant of VBC.

- **Collaborative Platforms:** Some industry groups propose creating multicompany vs payer platforms or risk pools. For instance, the idea of a "payers' license" pool (as was implemented for HepC in Louisiana) to spread risk across all payers is being studied (pubmed.ncbi.nlm.nih.gov). Similarly, cross-stakeholder consortia might handle outcomes measurement so individual plans don't each have to repeat work.

- **Integration with HTA and Guidelines:** There may be closer alignment of VBC with formal health technology assessments. Instead of a static price, reimbursement could be conditional on post-marketing evidence gathered via VBC, similar to "coverage with evidence development" policies. We might see official regulatory frameworks for such contracts (providing safe harbors and standardized processes).

Overall, **value-based contracting in pharmaceuticals remains a work in progress**. Its future success will hinge on scalable infrastructure, clear evidence of win-win scenarios, and sensible policy support. As many experts caution, it should complement – not replace – fundamental pricing reforms. But if properly implemented, it has potential to nudge the system toward paying for genuine patient benefit rather than mere pill distribution.

Conclusion

Value-based contracting and outcomes-based pricing in the pharmaceutical industry represent an innovative, if still emerging, approach to drug reimbursement. Rooted in the idea of paying for value rather than volume, these contracts theoretically promise to align incentives across stakeholders, promote patient-centered outcomes, and potentially control runaway drug costs. Our analysis has shown that while there is significant conceptual appeal and some early successes (e.g. diabetes and oncologic drug pilots), practical experience is mixed.

Empirical evidence to date indicates only modest impact on overall spending or healthcare value (pubmed.ncbi.nlm.nih.gov) (www.researchgate.net). Many agreements are narrowly targeted, confidential, and highly complex. The barriers – data gaps, administrative burden, legal hurdles, and patient turnover – are formidable. At the same time, stakeholder interest remains high. Payers continue to pilot and expand promising contracts, manufacturers to propose them as strategic tools, and policymakers to facilitate them (e.g. issuing safe harbor rules (www.cms.gov) and funding demonstration projects).

Importantly, value-based pricing models have been evolving. Beyond classic outcomes rebates, models like population subscriptions (Netflix pricing for cures) challenge traditional pricing paradigms. Advances in digital health and analytics may soon enable more sophisticated, real-time outcome measurement, making these models more operationally feasible. And as more breakthrough therapies emerge, the pressure on the system will likely keep value-based approaches on the agenda.

The overall conclusion is cautious: **value-based drug contracts are a promising direction but not a panacea.** They require rigorous design, robust data, and commitment by all parties. To date, the most credible review cautioned that “their impact [on spending] is unclear” and recommended continuing to test and evaluate them (pubmed.ncbi.nlm.nih.gov). As one expert put it, outcomes contracts might not “move us closer to value” on their own (www.drugpricinglab.org) unless embedded in a broader value-conscious framework. For healthcare systems, the key will be to integrate lessons learned, scale successful pilots where possible, and maintain transparency about what works.

In summary, outcomes-based pricing models in pharmaceuticals are **at a pivotal inflection point**. If the health ecosystem can solve the practical challenges and truly link payment to patient benefit, these contracts could become a standard part of the value calculus. But without that, there is risk they remain isolated anecdotes. Vigilant evaluation, stakeholder collaboration, and adaptive policy will determine whether value-based contracting realizes its promise of better outcomes at sustainable costs.

References: See inline citations above for full source details (links to studies, policy documents, and news reports). Each claim in this report is backed by credible literature and reports from health care research (e.g. journals, industry analyses {{ (www.ajmc.com) (www.contractpharma.com) (www.pharmexec.com)}}, policy and regulatory sources {{ (www.cms.gov)}}, and expert articles {{ (www.pharmacytimes.com) (www.mckinsey.com)}}). Additional references include health system case studies and press releases (e.g. Kaiser Health

News on Hepatitis C models (www.fiercepharma.com)). All cited content is publicly available outside the Intuition Labs site.

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