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Precision medicine financing models for gene and cell therapies

Tolulope Jagun *

Commercial and Revenue Manager, Sanofi, Nigeria.

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Abstract

The rapid expansion of precision medicine, particularly gene and cell therapies, has introduced transformative treatment options for previously intractable diseases. These therapies often curative in a single administration represent a paradigm shift from chronic management toward long-term or lifetime health restoration. However, their exceptionally high upfront costs create unprecedented financial challenges for health systems, insurers, and patients. Traditional reimbursement models, built around recurring payments for chronic care, are poorly aligned with the economic profile of one-time, high-value interventions. As a result, new financing strategies are urgently needed to ensure that curative therapies remain accessible while preserving the incentives necessary for continued biomedical innovation. Sustainable reimbursement frameworks increasingly emphasize value-based and performance-linked structures. Outcomes-based payment agreements tie reimbursement to measurable clinical improvements, reducing payer risk in cases of uncertain durability. Such models also encourage manufacturers to ensure long-term efficacy monitoring. Annuity-style payment mechanisms distribute costs over multiple years, aligning payments more closely with therapeutic benefit and improving budget predictability for healthcare systems. Hybrid models combining risk-sharing, milestone-based payments, and reinsurance pools offer additional pathways to address uncertainties around long-term effectiveness and affordability. From a macroeconomic perspective, sustainable financing for gene and cell therapies requires multi-stakeholder coordination, robust real-world evidence infrastructures, and policy reforms enabling flexible contracting and data sharing. At a microeconomic level, implementation must account for patient access equity, provider readiness, and actuarial forecasting of therapy lifespans. Ultimately, precision medicine financing models must balance affordability, sustainability, and innovation incentives to ensure that life-altering gene and cell therapies reach all eligible patients without destabilizing healthcare budgets.

Keywords: Precision medicine financing; Gene and cell therapies; Outcomes-based reimbursement; Annuity payment models; Sustainable healthcare economics; Value-based innovation

1. Introduction

1.1. Background: The Rise of Precision Medicine

Precision medicine has rapidly shifted from a conceptual aspiration to a clinical reality, reshaping how diseases are diagnosed, stratified, and treated across multiple therapeutic domains [1]. Advances in genomic sequencing, biomarker discovery, and computational analytics have enabled clinicians to identify molecular subtypes that respond differentially to targeted therapies, creating far more individualized care pathways than those used in traditional treatment frameworks [2]. This shift has accelerated especially in oncology, rare diseases, and inherited disorders, where understanding gene-level mechanisms can dramatically improve therapeutic outcomes [3]. As clinical trials increasingly adopt biomarker-guided designs, regulators and payers have begun adjusting frameworks to evaluate therapies that demonstrate high efficacy in small, genetically defined patient groups [4]. Precision diagnostics including liquid biopsies, multi-omics profiling, and AI-enhanced risk prediction allow earlier detection and better treatment

* Corresponding author: Tolulope Jagun

selection, reducing exposure to ineffective or toxic interventions [5]. The convergence of these technologies with advanced biologics, such as gene editing and engineered cell platforms, has pushed the boundaries of therapeutic innovation. Together, these advances mark a fundamental realignment of medicine away from population-level averages toward biologically informed personalization, setting the stage for disruptive shifts in healthcare financing, regulatory oversight, and long-term patient management strategies [6].

1.2. Economic Disruption Created by Gene and Cell Therapies

Gene and cell therapies introduce a level of economic disruption unprecedented in modern biopharmaceutical markets because they redefine the very nature of treatment value delivery [7]. Unlike chronic therapies that generate recurring revenue over years, many gene-based interventions are designed to deliver durable or curative benefits through a single administration, shifting revenue concentration to the moment of treatment [3]. This creates financial pressures on payers and healthcare systems unaccustomed to managing exceptionally high upfront expenditures concentrated within small patient populations [8]. Manufacturing complexity further contributes to elevated prices, as viral vectors, autologous cell expansion, and personalized manufacturing workflows require precision infrastructure and high-skilled labor [9]. At the same time, the societal and economic benefits of cures reduced downstream medical costs, restored productivity, and lifelong disease avoidance are substantial but difficult to quantify. These dynamics challenge traditional actuarial models and force payers to reconsider long-standing reimbursement structures [10].

1.3. The Financing Challenge: High Upfront Costs vs. Lifetime Value

The financing dilemma arises from the tension between immediate therapeutic cost and the diffuse, long-term value that gene and cell therapies generate across a patient's lifetime [2]. Payers must absorb substantial upfront payments despite uncertainty regarding durability, real-world effectiveness, and patient mobility between insurance plans [6]. These uncertainties complicate cost-effectiveness assessments that rely on long time horizons and stable population tracking [7]. Moreover, conventional reimbursement systems were built around chronic treatment paradigms in which spending is distributed incrementally rather than concentrated into a one-time curative expense [1]. Innovative financial mechanisms such as performance-based contracts, annuity-style payments, and pooled-risk models have emerged to bridge this gap, yet implementation remains inconsistent and administratively challenging across different jurisdictions [5]. The resulting financial friction shapes market access timelines, influences pricing negotiations, and determines whether health systems can sustainably adopt transformative therapies [4].

2. Economic foundations of gene and cell therapy financing

2.1. Cost Structure of Gene and Cell Therapies

The cost structure of gene and cell therapies is fundamentally different from that of traditional pharmaceuticals because these modalities require highly specialized scientific development, complex manufacturing environments, and stringent regulatory oversight [7]. Unlike small-molecule drugs produced through scalable chemical synthesis, these therapies rely on biological materials viral vectors, engineered cells, and tissue-derived substrates that introduce variability, labor intensity, and multi-step quality controls [8]. As a result, production processes are capital-intensive and operate with limited economies of scale, especially for autologous therapies manufactured individually for each patient [9]. Development timelines are also influenced by the need for sophisticated preclinical models and long-term safety monitoring. Even after approval, maintaining compliant production capacity adds ongoing fixed costs, given the stringent GMP standards required to preserve product integrity [10]. These features collectively shape price-setting strategies and influence global market access dynamics.

2.1.1. R&D Intensity and Manufacturing Complexity

R&D for gene and cell therapies involves iterative biological engineering, vector optimization, and extensive safety evaluation, leading to development expenditures significantly higher than those for conventional therapeutics [11]. Manufacturing requires highly controlled environments equipped with bioreactors, viral vector purification systems, and closed-cell processing suites, all of which contribute to elevated capital costs [12]. Each batch must undergo exhaustive testing for potency, purity, and genomic stability, resulting in labor-intensive workflows and long release timelines. The specialized nature of the workforce further raises costs, as bioengineers and GMP-trained technicians are needed at each production stage. These factors combine to create a cost base that remains structurally rigid and resistant to large-scale cost reduction [9].

2.1.2. One-Time Administration and Lifetime Benefit Models

Gene and cell therapies often aim to deliver durable or curative benefit through a single administration, concentrating economic value at the point of treatment [13]. While lifetime health gains may be substantial reducing the need for chronic medication, hospitalizations, or supportive therapies quantifying these benefits requires assumptions about long-term durability, which introduces uncertainty for both manufacturers and payers [7]. The one-time cost structure means manufacturers must recover R&D and production expenses upfront, contributing to high launch prices. Yet the long-term societal value, including restored productivity and reduced caregiver burden, may justify substantial investment if outcomes prove durable [15]. The challenge lies in balancing immediate financial pressure with projected lifetime economic benefit.

2.2. Risk, Uncertainty, and Budget Impact for Payers

Payers face significant uncertainty when evaluating gene and cell therapies, as clinical trials typically involve small cohorts, limited follow-up duration, and heterogeneous patient presentations [14]. This makes it difficult to assess long-term durability, adverse events, and downstream medical savings with high confidence. Budget impacts are further amplified because costs are concentrated at the time of administration rather than distributed over years as with chronic treatments. As high-cost therapies enter the market more frequently, health systems must reconcile limited annual budgets with the need to provide timely access to transformative treatments [16]. These pressures highlight the importance of predictive modeling, risk-sharing contracts, and actuarial frameworks that can adapt to the unique financial profile of curative therapies.

2.2.1. Durability of Response Uncertainty

Because durable outcomes may take years to fully manifest, payers must make reimbursement decisions despite incomplete certainty regarding long-term efficacy [8]. Variability in patient genetics, disease stage, and immune response can influence treatment durability, meaning real-world outcomes may diverge from early clinical trial data [11]. Unexpected late-onset adverse effects or diminishing therapeutic effect could alter the value proposition significantly. As a result, payers often rely on outcome-based contracts or conditional reimbursement models to manage durability risk [17]. These mechanisms link payment to long-term treatment performance, aligning financial exposure with verified clinical benefit.

2.2.2. Actuarial Challenges in Rare Disease Populations

Rare disease populations pose unique actuarial challenges because small patient numbers and heterogeneous disease trajectories produce significant variability in cost-effectiveness estimates [14]. Traditional actuarial tools depend on large sample sizes and stable epidemiological patterns, neither of which applies to ultra-rare conditions. Patient mobility across insurance plans further complicates cost allocation, as one payer may bear the upfront cost while another reaps the long-term savings [10]. This misalignment creates incentives for short-term decision-making that may limit access to curative therapies. Advanced forecasting models that incorporate genomic markers, progression patterns, and cross-plan risk pooling are becoming increasingly important for improving actuarial accuracy [12].

2.3. Market Access Pressures and Global Pricing Variability

Market access frameworks vary widely across countries, resulting in significant pricing differences for gene and cell therapies. High-income markets with established HTA systems evaluate value based on cost-effectiveness thresholds, willingness-to-pay metrics, and long-term budget impacts, while lower-income regions face affordability constraints despite high clinical need [15]. Manufacturers must navigate diverse regulatory timelines, data requirements, and evidence standards, prolonging the path to global availability. Pricing negotiations are further influenced by local epidemiology, reimbursement capacity, and societal value frameworks that weigh rarity, disease severity, and unmet need differently across jurisdictions [9]. In some markets, differential pricing or managed access agreements help bridge affordability gaps, but implementation remains inconsistent. As more therapies enter the pipeline, global health systems face increasing pressure to harmonize evaluation methods, reduce inequities, and ensure access without compromising financial sustainability [16].

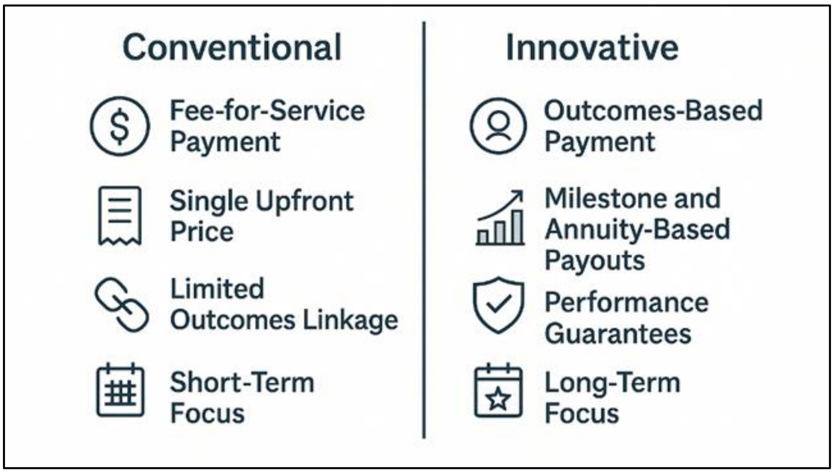

Figure 1 Comparative Overview of Conventional vs Innovative Gene Therapy Financing Models

3. Traditional and emerging financing models

3.1. Traditional Payment Models and Their Limitations

Traditional healthcare payment structures were designed for chronic medication regimens and episodic care interventions, making them poorly suited for the financial dynamics of high-cost, potentially curative gene and cell therapies [15]. The fee-for-service model reimburses based on volume, not outcomes, creating incentives that conflict with the value proposition of one-time transformative treatments. Because gene therapies concentrate cost at a single point in time, traditional payment approaches cannot effectively distribute financial risk or align reimbursement with long-term patient benefit [16]. Moreover, historical pricing frameworks assumed predictable treatment utilization patterns and relatively stable patient transitions across insurance plans. These assumptions break down in rare disease populations and in therapeutic categories where durable benefits extend for decades [17]. As a result, payers face immediate budget strain while the therapeutic value unfolds far beyond the year of expenditure. Such misalignment limits patient access, delays market uptake, and places downward pressure on innovation when funding systems cannot accommodate new cost structures [18]. To manage these pressures, health systems must evolve toward models that better account for durability uncertainty, financial risk distribution, and shifting clinical responsibilities across multi-year horizons.

3.1.1. Fee-for-Service Inefficiencies

Fee-for-service systems reward procedural activity rather than therapeutic effectiveness, creating inefficiencies when applied to curative gene therapies [19]. Under this model, reimbursement does not adjust based on durability, reduction in lifetime healthcare utilization, or cure-level outcomes. Because the cost of gene therapy is incurred upfront, payers shoulder immediate financial exposure without mechanisms to recoup value when long-term cost savings accrue. Inefficiencies also arise from fragmented care delivery, where providers are incentivized to deliver repeat interventions rather than durable solutions. Additionally, fee-for-service does not support longitudinal follow-up essential for monitoring gene therapy safety and real-world durability, leaving structural gaps between clinical value and financial accountability frameworks [20].

3.1.2. Current Limitations in Chronic-Care Cost Spreading

Traditional cost-spreading mechanisms evolved around chronic treatments with predictable monthly or annual expenditures [21]. Because gene therapies invert this structure requiring one-time payment for lifetime value cost-distribution tools become ineffective. Chronic-care models assume stable enrollee retention, yet high patient mobility means the payer funding treatment may not retain the long-term economic benefit [22]. Actuarial assumptions underpinning these models also fail to account for rare disease volatility or dramatic year-to-year enrollment swings. As a result, chronic-care cost distribution cannot absorb large transformational therapy expenses without creating volatility in premiums, budgets, or risk pools. These limitations highlight the need for alternative financing mechanisms tailored to the unique economic profile of curative interventions [23].

3.2. Outcomes-Based Reimbursement Models

Outcomes-based reimbursement frameworks realign financial incentives around verified clinical performance rather than payment at the moment of administration. These models emerged as a response to the uncertainty surrounding long-term durability in gene and cell therapies, providing a mechanism to link reimbursement to measured benefit rather than assumptions embedded in early clinical data [17]. By conditioning payment on milestones or sustained response, these agreements lower payer exposure while encouraging manufacturers to maintain accountability for therapeutic performance [24]. Outcomes-based models also address misalignments created by high upfront costs, enabling staged or conditional payments tied to observable patient outcomes. This approach enhances affordability, reduces financial risk, and increases willingness among payers to adopt transformative therapies despite limited long-term data.

Furthermore, outcomes-based frameworks require robust data infrastructure, including registries, digital monitoring platforms, and biomarker-guided performance metrics that can verify treatment impact over multi-year periods [18]. They support a shift toward real-world evidence as a basis for reimbursement decisions and encourage collaboration between manufacturers, regulators, and payers. As gene therapy portfolios expand, outcomes-based contracts will become critical tools for balancing innovation with financial sustainability, particularly in rare disease populations where clinical certainty is inherently limited.

3.2.1. Milestone-Based Payments (Pay-for-Performance)

Milestone-based payment structures link reimbursement to predefined clinical benchmarks, such as symptom improvement, biomarker normalization, or reduction in disease burden measured over a specific timeframe [19]. Rather than paying the full therapy price immediately, payers release partial payments as patients meet successive outcome targets. This pay-for-performance approach mitigates uncertainty by ensuring manufacturers only receive full compensation if real-world benefits align with clinical expectations. Milestones also introduce flexibility if intermediate outcomes fall short, remaining payments may be reduced or withheld. This model is particularly effective for therapies with early signs of effect but uncertain long-term durability. It strengthens transparency by aligning financial flows with clinical milestones and reducing payer exposure to underperforming treatments [22].

3.2.2. Durable Response Guarantees and Performance Rebates

Durable response guarantees extend the pay-for-performance concept by tying payment to sustained benefit over multi-year horizons [16]. If patient outcomes deteriorate prematurely, the manufacturer may issue rebates or refunds that compensate payers for lost therapeutic value. These models are especially relevant for gene therapies intended to provide long-term stability or functional cure. By tying payment to durability, manufacturers share part of the financial risk associated with uncertain long-term performance. Performance rebate structures also allow payers to manage budget impact without compromising access for patients who could benefit substantially from early treatment [21]. Durable response guarantees foster trust between stakeholders and create a shared incentive to support ongoing patient monitoring, real-world evidence generation, and long-term follow-up.

3.3. Annuity and Installment Payment Structures

Annuity-based payment models distribute the cost of gene therapy over multiple years, allowing health systems to align financial outflows with realized therapeutic value rather than incurring a single massive expenditure [20]. These models mimic amortization frameworks commonly used in capital finance, reducing short-term budget stress while preserving access. Because costs are spread across predictable intervals, payers face less budget volatility and can incorporate long-term planning into coverage decisions. Manufacturers benefit from broader adoption and improved payer willingness to implement high-value technologies. When structured effectively, annuity models balance innovation incentives with affordability constraints across diverse health systems.

Installment structures also allow flexible adaptation to outcomes-based components payments may be suspended or modified if durability declines. Such hybrid financing supports risk-sharing and encourages ongoing monitoring because financial obligations remain tied to therapeutic performance. For rare diseases with highly variable trajectories, flexible amortization frameworks reduce the financial friction that might otherwise limit patient access and market penetration.

3.3.1. Multi-Year Amortization Models

Multi-year amortization distributes gene therapy costs over several budget cycles, reducing immediate fiscal shock and allowing health systems to preserve stability in premiums or public budgets [18]. Payments typically span three to seven years, aligning with both clinical follow-up intervals and actuarial planning cycles. This model helps reconcile the disconnect between one-time costs and long-term value by matching financial outflows to incremental patient benefit [23]. It also ensures that new treatments do not consume disproportionate shares of annual budgets, especially for small health plans. Amortization thus supports predictable investment and reduces barriers to early adoption.

3.3.2. Hybrid Annuity + Outcomes Guarantees

Hybrid models integrate amortization with outcomes-based guarantees, creating financing systems that adjust payments based on durability performance [24]. Under this structure, installment payments continue only if patients maintain clinical response, ensuring that payers do not overspend for diminishing benefit. This approach combines financial flexibility with accountability, preserving innovation incentives while protecting payer budgets. Hybrid systems are particularly valuable for therapies with uncertain long-term trajectories, as they link payment to measurable, sustained outcomes. By merging cost-distribution and performance safeguards, these models represent one of the most adaptable financing mechanisms in the evolving gene therapy landscape [17].

4. Data infrastructure for evidence generation and payment validation

4.1. Real-World Evidence (RWE) Systems

Real-world evidence (RWE) systems are becoming central to validating the long-term performance of gene and cell therapies, especially as many products enter the market with limited durability data from small clinical trials [22]. Because long-term outcomes extend far beyond controlled trial environments, payers and regulators increasingly depend on RWE to assess whether therapeutic effects persist, whether new safety signals emerge, and how interventions affect healthcare utilization patterns over time [23]. RWE systems integrate diverse data sources registries, electronic health records, genomic databases, claims data, and patient-reported outcomes to produce a comprehensive view of treatment impact outside the confines of early trial cohorts [24]. For curative treatments with multi-decade benefit horizons, continuous evidence generation is essential to support outcomes-based reimbursement, recalibrate actuarial assumptions, and adjust performance-linked payment schedules. As more gene therapies launch globally, scalable RWE infrastructure will determine whether health systems can assess real-world durability with confidence, maintain financial safeguards, and ensure equitable patient access [26]. These systems represent a foundational pillar in balancing innovation with long-term accountability and economic sustainability.

4.1.1. Post-Market Monitoring Systems for Long-Term Outcomes

Post-market monitoring enables health systems to track multi-year outcomes, adverse events, and real-world durability signals beyond the limited timelines of pivotal trials [25]. Because gene and cell therapies may demonstrate unexpected late-phase safety issues or declining efficacy, continuous surveillance is necessary to validate their lifetime value propositions. Monitoring frameworks incorporate standardized follow-up intervals, biomarker assessments, longitudinal registries, and cross-institutional data feeds that collectively reveal how therapies behave across diverse patient populations [27]. These systems also support outcomes-based payment agreements by providing objective evidence linking reimbursement to verified clinical milestones. For rare diseases with small patient populations, pooled international registries further expand visibility into long-term patterns and variability.

4.1.2. Data Standardization and Interoperability Challenges

Despite advances in digital infrastructure, interoperability challenges remain a major barrier to robust RWE generation [24]. Variations in data formats, inconsistent coding practices, and fragmented registry structures make it difficult to aggregate real-world outcomes across institutions or countries [28]. Gene therapy monitoring requires harmonized genomic data, biomarker records, imaging metrics, and long-term clinical assessments, yet many systems remain siloed or incompatible. Without standardized data models, evidence generation becomes slower, more expensive, and prone to analytical gaps. Efforts such as common data models, shared terminologies, and multi-stakeholder interoperability frameworks are essential to improving evidence quality and ensuring that RWE can support reimbursement decisions, safety assessments, and policy frameworks with greater precision [29].

4.2. Digital Health Integration and Biomarker Tracking

Digital health technologies increasingly support gene and cell therapy management by enabling continuous monitoring, remote assessment, and automated detection of clinically relevant changes [22]. Mobile health platforms, wearable sensors, connected diagnostic kits, and remote-capture biomarker tools provide a steady flow of patient-level data that complements traditional clinic-based assessments. Such systems significantly reduce follow-up burdens for patients with rare or debilitating conditions, while offering payers and regulators real-time insight into therapeutic performance across diverse settings [26]. When combined with genomic and laboratory data, digital health platforms support richer patient stratification, early risk identification, and alignment of clinical outcomes with value-based reimbursement structures. Digital ecosystems also strengthen patient engagement by providing reminders, adherence support, and symptom-tracking tools that enhance overall treatment success. As gene and cell therapies expand into broader clinical use, the ability to integrate digital health monitoring into reimbursement, safety, and long-term evidence frameworks will become increasingly essential for demonstrating effectiveness and financial accountability.

4.2.1. Genomic, Phenotypic, and Biological Marker Tracking

Biomarker tracking allows clinicians and payers to verify whether gene and cell therapy mechanisms remain active over time, providing objective signals of durability [27]. Genomic markers reveal vector integration stability or correction durability, while phenotypic markers capture functional recovery trends. Biomarkers such as enzyme activity, protein expression, metabolic levels, or immune signatures provide high-resolution indicators of whether clinical responses are sustained. These data streams complement clinical outcomes and help refine long-term payment schedules, especially when used in performance-linked contracts [28]. Because small deviations in biomarker trajectories may precede clinical relapse, continuous biomarker monitoring supports early intervention and improved patient safety.

4.2.2. AI-Supported Outcome Adjudication Systems

AI-enabled adjudication platforms analyze multi-modal data clinical results, biomarkers, imaging, and patient-reported outcomes to determine whether real-world results meet predefined performance thresholds [30]. Such systems enhance the consistency and objectivity of outcome verification by reducing human variability in clinical interpretation. They also accelerate reimbursement cycles by providing automated, evidence-based assessments for milestone-based or durability-linked payment agreements [29]. For rare diseases with heterogeneous presentations, AI improves sensitivity in detecting subtle changes while supporting scalable monitoring across geographically dispersed populations. These capabilities strengthen the integrity of outcomes-based reimbursement frameworks and reduce administrative burden for payers and manufacturers.

4.3. Health Technology Assessment (HTA) Evolution

Health Technology Assessment (HTA) frameworks are evolving to address the unique characteristics of gene and cell therapies, which challenge traditional cost-effectiveness and budget-impact methodologies [23]. Because these therapies often deliver benefits over decades, HTA models must account for uncertainties in durability, patient heterogeneity, and real-world treatment patterns that extend far beyond clinical trials [26]. Conventional discounting methods, utility mapping, and extrapolation techniques may undervalue long-term curative benefit or fail to capture productivity gains and caregiver burden reduction. New HTA approaches incorporate broader societal perspectives, lifetime modeling, and dynamic updating of cost-effectiveness estimates as RWE accumulates [22]. International HTA bodies are also experimenting with modular evidence submissions, adaptive appraisals, and value-sharing mechanisms aligned with outcomes-based financing. As regulatory pathways shift toward accelerated approvals, HTA evolution becomes essential for ensuring that pricing decisions reflect both scientific complexity and long-term economic impact. These changes ultimately support more equitable and sustainable patient access across diverse health systems.

Table 1 Key Data Types Required for Validating Gene & Cell Therapy Performance

Data Type	What It Captures	Purpose in Validation
Clinical Outcomes	Functional change, relapse events, symptom improvement	Confirms real-world therapeutic benefit
Safety Data	Adverse events, late toxicities	Ensures long-term safety and monitors emerging risks
Biomarkers & Genomics	Expression levels, enzyme activity, corrected protein function	Verifies biological durability and mechanism of action
Healthcare Utilization	Claims, hospitalizations, medication use	Measures economic impact and avoided chronic care costs
EHR Data	Labs, vitals, imaging, clinical notes	Supports longitudinal follow-up and contextual outcome assessment

Patient-Reported Outcomes (PROs)	Quality of life, daily functioning	Captures patient-centered benefit not shown in labs alone
Registry / Cohort Data	Standardized long-term population data	Enables rare-disease tracking and long-horizon durability analysis
Digital Monitoring	Wearables, remote biometrics, adherence	Provides continuous real-time evidence for outcome triggers
Contract Verification Data	Milestone logs, audit trails	Enables performance-based payment and accountability

5. Regulatory, legal, and policy frameworks

5.1. Regulatory Pathways and Post-Approval Obligations

5.1.1. Accelerated Approvals: Implications for Financing

Accelerated approval pathways allow gene and cell therapies to enter the market based on surrogate endpoints rather than fully mature clinical outcomes, speeding access but creating financial uncertainty for payers [28]. Because long-term durability evidence may not be available at launch, early reimbursement negotiations must rely on predictive models and limited trial data. Manufacturers face pressure to price products to reflect high development costs, while payers attempt to mitigate risk through conditional or milestone-linked agreements [30]. Accelerated approvals also compress negotiation timelines, forcing stakeholders to establish financing frameworks before real-world evidence is available. As a result, health systems must adopt flexible payment mechanisms capable of incorporating new data as post-market findings evolve across multi-year periods [32].

5.1.2. Mandatory Long-Term Follow-up Frameworks

Long-term follow-up obligations extend for many years after approval, requiring ongoing data collection to monitor durability, late-onset toxicities, and real-world safety signals [33]. These obligations create operational and financial challenges because monitoring must continue regardless of payer turnover or patient mobility. Regulatory agencies increasingly require structured reporting intervals, standardized data formats, and active participation in registries to ensure that evidence accumulates consistently across treatment centers [29]. For payers, long-term monitoring influences risk-sharing design, as payments may be adjusted based on multi-year outcome verification. Manufacturers must support systems that capture clinical and biomarker data beyond initial treatment, aligning post-approval obligations with reimbursement frameworks that depend on demonstrable, sustained benefit over time [35].

5.2. Legal Barriers to Innovative Payment Contracts

5.2.1. Anti-Kickback and Medicaid Best Price Constraints

Many innovative payment models face limits under anti-kickback statutes and Medicaid Best Price requirements, which restrict how manufacturers structure rebates, performance guarantees, and multi-year discount mechanisms [30]. Best Price rules, in particular, complicate outcomes-based agreements because a single deep rebate triggered by underperformance could reset national pricing benchmarks. Anti-kickback concerns arise when financial arrangements between payers, providers, and manufacturers risk being interpreted as inducements rather than value-linked payment structures [28]. These constraints force stakeholders to adopt legally compliant contract designs that maintain flexibility for outcomes verification without triggering punitive pricing or compliance implications [34].

5.2.2. Cross-Jurisdictional Contracting Hurdles

Cross-jurisdictional agreements are difficult to implement because national, regional, and institutional regulations vary widely in how they define value-based payment structures [31]. Differences in privacy law, data-sharing permissions, reimbursement authority, and registry participation limit the scalability of multi-payer or multi-country agreements. Gene therapy financing must often be negotiated separately with each payer, leading to fragmented adoption and inconsistent access. Additionally, administrative requirements for monitoring outcomes across borders can be costly and complex. Harmonization efforts remain limited, forcing health systems to navigate regulatory landscapes that slow the diffusion of innovative payment approaches and hinder coordinated long-term evidence collection [29].

5.3. National vs. Regional Policy Approaches

National policies often establish broad reimbursement frameworks, HTA criteria, and safety standards, but regional authorities typically manage implementation, leading to variability in patient access and financing structures [32]. For gene and cell therapies, national-level strategies may articulate principles for affordability and value assessment, yet regional payers must translate these principles into operational payment models that align with local budgets and population needs [35]. This division can create disparities when wealthier regions adopt advanced financing mechanisms more rapidly than resource-constrained areas. Internationally, countries differ in their willingness-to-pay thresholds, data requirements, and long-term evidence expectations, further contributing to global variability [28]. Some nations rely heavily on centralized negotiations, while others empower local authorities to contract independently. As more gene therapies reach market, policy coherence becomes increasingly important to prevent inequitable access and ensure that financing models reflect shared national priorities rather than regional budget limitations [33].

6. Payer adoption and health system readiness

6.1. Budget Impact Modeling for High-Cost Therapies

6.1.1. Forecasting Rare Disease Prevalence and Uptake

Budget impact models for gene and cell therapies depend heavily on accurate forecasting of rare disease prevalence and expected treatment uptake, yet these estimates are often constrained by limited epidemiological data [32]. Small patient populations lead to volatility in year-to-year enrollment, complicating actuarial projections for payers. Machine learning–based forecasting tools increasingly supplement traditional epidemiology by integrating genomic screening rates, newborn testing penetration, and real-world diagnostic patterns to anticipate shifts in detection and eligibility [35]. Adoption assumptions must also account for diagnostic delays, referral inefficiencies, and regional disparities in specialty-center capacity. Because even a small deviation in case numbers can create disproportionate budget effects, payers rely on adaptive forecasting that recalibrates as new evidence emerges.

6.1.2. Financial Risk-Sharing Across Population Pools

To manage the financial exposure associated with high-cost one-time therapies, many health systems explore risk-sharing across broader population pools rather than confining costs to individual payers or small insurance plans [36]. Multi-payer pooling, national reinsurance arrangements, and cross-plan contribution models reduce volatility by distributing risk across larger populations. These mechanisms are particularly important when individual health plans face unpredictable spikes in eligible patients. Population-based pooling also aligns incentives by ensuring that long-term value and savings such as reduced lifetime treatment costs are not lost due to patient mobility across plans or regions [33]. Without broader risk-sharing frameworks, budget impact becomes a major barrier to equitable patient access.

6.2. Infrastructure Requirements for Performance-Based Contracts

6.2.1. Claims, Medical Records, and Genomic Data Integration

Performance-based contracts require integrated data architecture capable of linking claims, clinical records, genomic profiles, and longitudinal monitoring data across provider networks [38]. Fragmentation in health information systems creates gaps that undermine outcome verification and delay payment reconciliation. Effective integration depends on standardized data formats, interoperable EHR systems, and secure governance frameworks that allow multi-stakeholder access while maintaining compliance with privacy regulations. Genomic data adds complexity because it requires specialized storage, high-resolution annotation standards, and linkage to phenotype or outcome markers. Without harmonized integration, performance-based agreements cannot reliably confirm whether real-world results meet contractually defined milestones [34].

6.2.2. Verification of Long-Term Response or Recurrence

Long-term verification mechanisms ensure that payments remain aligned with sustained therapeutic benefit rather than early signals alone [32]. These mechanisms depend on biomarkers, imaging data, clinical outcome scores, and recurrence surveillance protocols that persist long after administration. Because durability may extend for decades, longitudinal evidence systems must maintain continuity despite payer turnover, relocation, or care-fragmentation events [39]. Verification also requires automated analytics that detect deviation from expected response profiles, flag early recurrence, and trigger contractually defined payment adjustments. High-quality longitudinal verification remains one of the most resource-intensive components of performance-based reimbursement for curative therapies.

6.3. Payer Organizational Capability and Innovation Culture

Payer adoption of innovative financing models depends not only on legal or economic feasibility but also on organizational readiness, data capacity, and willingness to embrace experimental contracting structures [37]. Health plans with advanced analytics teams and integrated informatics systems adopt performance-based agreements significantly faster than organizations constrained by legacy systems. Innovation culture plays a major role: payers willing to experiment with outcomes-based contracting, annuity payments, or hybrid financial models tend to develop internal talent pipelines, governance frameworks, and cross-functional teams dedicated to therapy evaluation and contract oversight [35]. Organizational capability also includes the ability to collaborate effectively with manufacturers, regulators, and providers on multi-year agreements that require shared data, coordinated monitoring, and flexible response to new evidence. In resource-limited settings, the absence of such infrastructure limits experimentation and perpetuates slower adoption cycles, reinforcing disparities in access to transformative therapies [40].

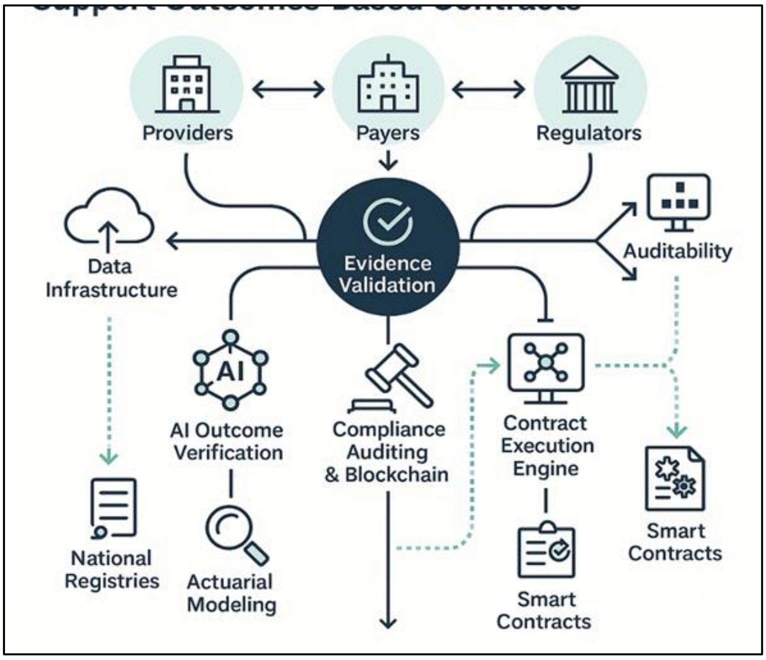

Figure 2 Health System Infrastructure Needed to Support Outcomes-Based Contracts

7. Manufacturer perspectives and innovation incentives

7.1. Aligning Pricing with R&D Recovery and Risk Exposure

7.1.1. Investment Recovery Timelines in One-Time Therapies

Manufacturers developing one-time gene and cell therapies face compressed revenue timelines because they cannot rely on recurring treatment cycles to gradually recover R&D and commercialization investments [34]. Instead, companies must recoup multi-year scientific, regulatory, and manufacturing expenditures at the point of administration, which elevates initial price requirements. Long development horizons, combined with high clinical attrition rates, intensify risk exposure and drive firms to structure pricing around projected lifetime therapeutic impact rather than short-term incremental benefit [36]. Additionally, small patient populations typical of rare disease markets reduce the potential to amortize development costs across large volumes. These economic dynamics mean investment recovery depends on early adoption, predictable reimbursement pathways, and alignment between price and long-term clinical value rather than traditional volume-based models [40].

7.1.2. Manufacturing Scale-up and Cost Decline Models

As manufacturing expands, gene therapy production may achieve modest cost reductions, but large-scale economies remain limited due to the biological complexity of viral vectors and engineered cells [35]. Unlike small-molecule production, which benefits from linear scale-up, gene therapy processes are constrained by batch variability, specialized labor, and intensive quality-control requirements [37]. Nevertheless, incremental efficiencies arise from platform-based vector production, automation of cell-handling steps, and optimized release testing protocols. Early commercial batches incur the highest costs, while later cycles may benefit from reproducibility improvements and supply-chain learning effects [42]. These constrained yet meaningful cost-decline models influence pricing strategy by enabling gradual adjustment as manufacturing maturity increases, though reductions rarely mirror the steep declines observed in conventional pharmaceuticals.

7.2. Balancing Access, Affordability, and Commercial Sustainability

7.2.1. License-Based and Subscription-Based Access Models

Emerging payment innovations such as license-based or subscription-based models aim to reconcile affordability concerns with manufacturers' need for predictable revenue streams [38]. Under license-based structures, payers acquire multi-year treatment rights for eligible patient groups at a fixed cost, spreading budget impact over time while securing broad access. Subscription models often described as "Netflix-style" arrangements offer unlimited treatment within a defined population for a negotiated annual payment, protecting payers from unpredictable spikes in eligible cases [43]. These models improve predictability and help manage high-cost therapies in rare disease markets where prevalence volatility drives actuarial instability. For manufacturers, subscription-based contracts encourage deeper market penetration and sustained collaboration with health systems, supporting long-term evidence development and risk-sharing mechanisms while maintaining commercial viability [45].

7.2.2. Portfolio Diversification and Volatility Mitigation

Manufacturers increasingly develop diversified therapeutic portfolios to balance commercial volatility in markets defined by small patient populations and uncertain long-term outcomes [34]. By investing across multiple disease areas, vector platforms, and therapeutic modalities, firms reduce dependency on a single high-cost therapy and improve resilience against clinical or regulatory setbacks [41]. Diversification also enables cross-portfolio learning, driving improvements in vector delivery, manufacturing reliability, and regulatory negotiation capacity. From a financial standpoint, a balanced portfolio mitigates unpredictable revenue cycles that arise when adoption depends heavily on payer readiness or outcomes-based contract performance [39]. This approach strengthens long-term commercial sustainability while facilitating continued investment in next-generation technologies, including in vivo editing and regenerative platforms. Diversification thus becomes an essential mechanism for stabilizing operations and advancing innovation in the rapidly evolving gene therapy sector [44].

8. Macroeconomic and societal implications

8.1. National Budget Sustainability and Long-Term Value Capture

8.1.1. Workforce Productivity Gains vs. Therapy Cost

Gene and cell therapies can generate substantial workforce productivity gains by restoring functional capacity in patients who would otherwise require lifelong medical support or experience chronic disability [37]. These economic benefits, however, diffuse across decades rather than immediately influencing annual budget cycles. Productivity improvements reduced absenteeism, fewer disability claims, and enhanced participation in the labor market rarely appear in payer-level cost models, creating a mismatch between who pays for therapy and who captures downstream societal value [39]. As a result, national health systems must consider broader macroeconomic metrics when evaluating affordability, placing workforce restoration within long-term value assessments [41].

8.1.2. Avoided Chronic Care Spending

Curative therapies may eliminate lifelong treatment expenses associated with chronic disease management, including specialist visits, hospitalizations, supportive therapies, and emergency interventions [38]. Despite these savings, the financial relief often materializes gradually and may benefit different payers than the one funding the initial therapy. Avoided spending is therefore difficult to incorporate into short-term budget planning, especially in systems with annualized budgeting requirements [44]. National-level models that capture multi-decade savings and reductions in disease burden improve visibility of the broader economic return on investment. Properly accounting for these avoided costs is essential for sustainable financing and equitable adoption of transformative genetic therapies [45].

8.2. Equity, Accessibility, and Global Health Considerations

8.2.1. Low- and Middle-Income Country Barriers

Low- and middle-income countries (LMICs) face significant structural constraints that limit access to advanced genetic medicines. High therapy prices intersect with limited insurance coverage, fragmented reimbursement systems, and insufficient diagnostic capacity, making adoption difficult even when disease prevalence is high [40]. Manufacturing facilities and vector production hubs are concentrated in high-income regions, creating supply bottlenecks and extended wait times for LMICs. In addition, gaps in regulatory infrastructure, shortage of trained clinicians, and limited cold-chain capacity further restrict clinical rollout. Many LMIC health systems must prioritize basic care needs, leaving few resources for high-cost innovations. Without coordinated global financing strategies, access disparities will continue to widen [42].

8.2.2. Ethical Issues in Differential Access

Ethical concerns arise when curative therapies are available in wealthier regions while patients in resource-constrained settings face prolonged delays or complete exclusion from access [37]. Differential access challenges fairness principles in global health, particularly for rare diseases that should not privilege geography over biological need. Even within wealthy countries, disparities emerge along racial, socioeconomic, and geographic lines due to uneven diagnostic rates, referral pathways, and payer coverage policies [43]. Ethical frameworks emphasize the importance of transparent decision-making, equitable reimbursement rules, and mechanisms that prevent wealth-based stratification of curative healthcare. Addressing these inequities requires policies that balance affordability, fairness, and global solidarity [45].

9. Future directions: next-generation financing models

9.1. Distributed Risk Pools and Reinsurance Mechanisms

Distributed risk-pooling mechanisms are becoming increasingly important as health systems confront the volatility posed by high-cost, one-time gene therapies [31]. Because individual payers may face unpredictable spikes in eligible patients, spreading cost exposure across larger pooled populations reduces catastrophic budget shocks. Multi-payer reinsurance models allow separate insurers, regional authorities, or national programs to collectively share financial risk, thereby stabilizing premiums and preserving access [33]. These arrangements also mitigate the problem of patient mobility, where one payer funds the therapy while another reaps the downstream clinical and economic benefits. National reinsurance frameworks can further enhance sustainability by establishing dedicated funds that accumulate reserves over time and activate when gene therapy claims arise [35].

Risk equalization systems already used in several national markets can be adapted to incorporate curative therapies by adjusting transfer rules based on disease severity, genomic eligibility, and projected long-term cost offsets. These systems ensure that high-cost cases do not disproportionately burden smaller plans or resource-limited regions. In addition, international pooling mechanisms, though still emerging, may help coordinate access for ultra-rare diseases where patient numbers are too small for sustainable local financing [37]. By smoothing financial volatility and aligning incentives across stakeholders, distributed risk pools strengthen affordability and promote equitable adoption of advanced genetic treatments [39].

9.2. Blockchain-Based Smart Contracts for Gene Therapy Payments

Blockchain-enabled smart contracts offer a future pathway for automating payment triggers, verifying performance milestones, and enforcing outcomes-based agreements for gene and cell therapies [32]. Because these therapies require long-term evidence generation, automated contract logic ensures that payments align precisely with clinical results captured through verified data streams. Smart contracts can integrate biomarker thresholds, recurrence indicators, or survival milestones, releasing payments only when predefined conditions are met [34]. This reduces administrative overhead and minimizes disputes between payers and manufacturers by ensuring transparent, tamper-resistant execution of complex financial arrangements [38].

Interoperable blockchain ledgers can also facilitate data exchange across clinics, national registries, and payers while maintaining confidentiality and compliance with regulatory standards. When combined with digital health tools and real-world evidence platforms, blockchain systems create a unified infrastructure for long-term monitoring, especially for outcomes that span multiple care sites or payer transitions [40]. Tokenized payment structures may eventually support micro-adjustments tied to incremental outcome verification, providing a more granular and adaptive financing model. Although early in adoption, blockchain-based architectures hold the potential to increase trust, streamline contract management, and strengthen accountability within next-generation gene therapy financing systems [36].

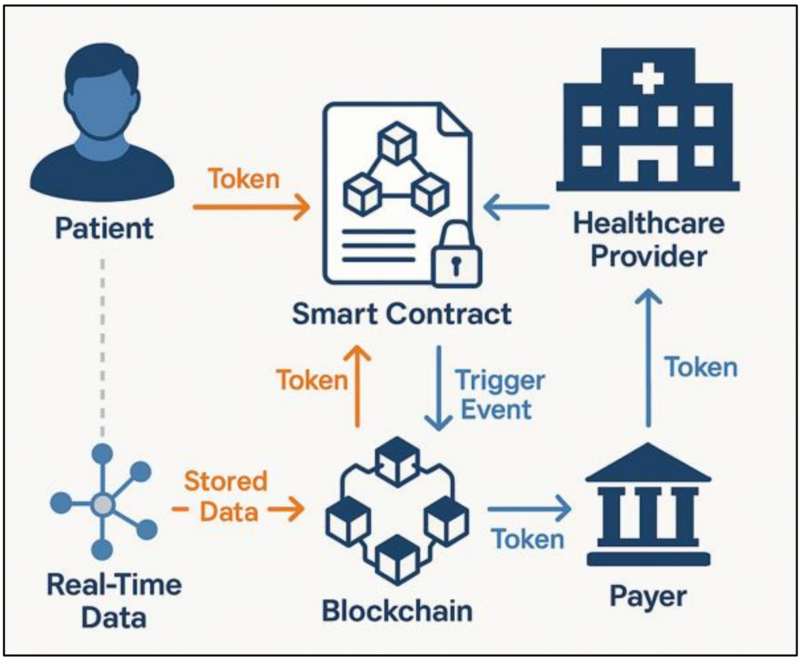

Figure 3 Future Architecture for Automated Gene Therapy Financing via Smart Contracts

10. Conclusion

10.1. Consolidated Insights

The financing landscape for gene and cell therapies is undergoing a profound transformation as health systems adapt to the unique economic and operational demands of curative, one-time treatments. Across the previous sections, several themes emerge clearly. First, traditional reimbursement structures are fundamentally misaligned with therapies that concentrate both cost and value at the moment of administration. This misalignment drives the need for annuity models, outcomes-based agreements, and risk-sharing mechanisms that better reflect long-term therapeutic benefit. Second, robust data infrastructure is essential for verifying durability, guiding actuarial planning, and supporting performance-linked payments across multi-year periods. Third, global inequities in diagnostic readiness, regulatory capacity, and affordability highlight the need for coordinated strategies that ensure uniform access. Together, these insights point toward a future in which financial sustainability, technological infrastructure, and equitable access structures must evolve simultaneously to support widespread adoption of advanced genetic medicines.

10.2. Strategic Priorities for Stakeholders

To build a sustainable ecosystem, stakeholders must prioritize several strategic actions. Payers should invest in data integration platforms, longitudinal monitoring capabilities, and analytic tools that reduce uncertainty in forecasting and performance assessment. Manufacturers must refine pricing strategies that balance investment recovery with affordability while embracing flexible financial models such as subscriptions, hybrid annuities, or outcomes-based agreements. Policymakers need to adapt regulatory and legal frameworks to enable innovative contracting, harmonize evidence requirements, and encourage broader risk pooling. Providers should strengthen diagnostic capacity, enhance patient tracking systems, and participate in data-sharing networks that support post-treatment follow-up. International collaborations will also be essential for ensuring global equity, especially for rare diseases with small, geographically dispersed populations. When aligned, these priorities form the foundation for a resilient and adaptable financing environment capable of supporting both innovation and widespread access.

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