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Elias C. Pittos & Joe DePinto

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Cell and gene therapies in managed care: US payer insights on coverage and financial risk

Elias C. Pittos and Joe DePinto

McKesson, Irving, TX, USA

ABSTRACT

Aims: Cell and gene therapies (CGTs) are increasingly transforming the treatment of serious and life-threatening conditions, offering durable and, in some cases, potentially curative benefit. However, high upfront costs paired with the expectation for long-term value realization create misalignment with conventional managed care and reimbursement models. Although innovative payment and risk-sharing strategies have been proposed, adoption remains limited. Understanding how payers are navigating these challenges is increasingly critical as CGTs continue to transition into established standards of care.

Methods: Sixty-minute, double-anonymized, semi-structured interviews were conducted to assess United States (US) payer perspectives toward CGT reimbursement. Participants were recruited *via* third-party vendors to minimize bias. Data collection included Likert-scale ratings and open-ended inquiries regarding access, formulary processes, and reimbursement frameworks.

Results: Twenty payer decision-makers were interviewed. While 17 viewed CGTs as among the most important medical innovations of our time, 18 agreed that the US healthcare system is not adequately prepared for broad CGT adoption. Top barriers to reimbursement include high upfront costs and long-term durability uncertainty. Preferred mitigation strategies include reinsurance/stop-loss and risk pools. Member portability and data tracking remain primary barriers to innovative payment models.

Limitations: Sample size may not represent all US payers. Qualitative study findings identify trends and consensus only.

Conclusions: Payers acknowledge the significant clinical promise of CGTs, but high upfront costs and long-term durability uncertainty continue to complicate coverage strategies and limit broader adoption. Ongoing evaluation of reimbursement frameworks, financing strategies, and emerging long-term evidence may help characterize how coverage and payment models evolve as the CGT landscape expands.

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Introduction

The emergence of cell and gene therapies (CGTs) has fundamentally redifined treatment landscapes across a range of serious and life-threatening conditions, including cancers, rare diseases, and genetic disorders[1,2]. The field continues to advance rapidly, with more than 2,000 products in development and 48 CGTs approved by the U.S. Food and Drug Administration (FDA) as of December 31, 2025[3,4]. Many CGTs are designed as one-time or short-course interventions with the potential to deliver durable and, in some cases, potentially curative, clinical benefit. As clinical evidence accumulates and indications expand, CGTs are increasingly being positioned as standard of care across a growing number of disease states.

CONTACT Elias C. Pittos elias.pittos@mckesson.com McKesson, Irving, TX, USA.

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However, the rapid pace of development and the novel nature of these treatments have introduced unprecedented challenges for traditional managed care frameworks, which have been largely designed for chronic or high-volume drug therapy utilization. One of the primary challenges lies in the concentration of costs associated with these therapies, as the full cost of treatment is often incurred upfront after a single episode rather than distributed over an extended treatment period[5]. The one-time cost for a single administration of many CGTs typically ranges from several hundred thousand dollars to over $4 million per treatment[6,7]. This cost profile creates uncertainty for payers, particularly in the setting of member turnover across health plans, where the payer that finances the treatment may not realize the long-term clinical and economic benefits when patients subsequently switch coverage[8]. Limited availability of multi-year long-term data at product approval also complicates risk assessments and makes it difficult for payers to justify substantially high, one-time payments.

In response to these challenges, many innovative payment and financing models have been proposed to better align reimbursement with the value profile of CGTs. These strategies seek to mitigate financial impact by linking payment to clinical performance or distributing financial risk over time. Emerging models include outcomes-based agreements (OBAs), in which reimbursement is contingent on achieving predefined clinical endpoints, as well as annuity or installment-based payment arrangements that spread costs across multiple years[9]. Additional strategies, such as risk-pooling and reinsurance mechanisms, have also been explored to address the budgetary impact associated with treating small patient populations with high-cost therapies. While these models offer potential pathways to improve affordability, widespread adoption remains limited, and continued evaluation and adaptation of reimbursement frameworks are needed as the field evolves[10,11].

Given the continued growth of the CGT market, understanding how payers are adapting to the realities of CGT utilization remains an important area of focus. This study draws on in-depth interviews with senior payer decision-makers across a broad spectrum of United States (US) health plans. By characterizing payer perspectives on the operational, economic, and policy factors influencing CGT coverage and adoption, this analysis aims to provide insight into how payers are evaluating the challenges and opportunities associated with CGT reimbursement in the US healthcare system.

Methods

Study design

A qualitative study using semi-structured, double-anonymized interviews was conducted to explore US payer perspectives on CGT reimbursement and financial risk management. The study incorporated qualitative open-ended questions and quantitative Likert-scale ratings to contextualize payer perspectives and describe areas of agreement or divergence. The identity of the study sponsor was not disclosed to the participants; likewise, participant identities were not disclosed to the sponsor. The study protocol was reviewed by the Western Institutional Review Board (WIRB)-Copernicus Group (WCG IRB) and determined to be exempt from IRB oversight.

Research team

Interviews were conducted by one trained male PhD-level researcher employed by the third-party research vendor as a strategy consultant. The interviewer had prior experience conducting more than 200 primary market research interviews with payers, physicians, and other healthcare professionals and had previously contributed to published qualitative research. The study authors did not conduct the interviews and did not know the identities of participating payer representatives.

The interviewer had no prior relationship with study participants before the interviews were conducted. Participants were informed that the interview was being conducted on behalf of an undisclosed client seeking to understand payer perspectives on CGTs. Consistent with the double-anonymized design, only de-identified information was provided to the sponsor and authors for analysis and reporting.

Participant selection and recruitment

Participants were recruited by a third-party vendor using curated expert panels and manual outreach through professional registries. Potential participants were approached by email or telephone and screened using a standardized questionnaire to confirm eligibility. The recruitment vendor maintained participant contact information and managed scheduling.

Payer representatives were screened using a standardized questionnaire to ensure they possessed high-level decision-making authority regarding CGT coverage. Eligible participants were required to hold a leadership role with direct responsibility for CGT coverage decisions at a US-based commercial or government payer or integrated delivery network (IDN). Screening criteria included: (1) current oversight of CGT coverage policies, (2) a self-reported proficiency rating of 6 or 7 (on a 7-point scale) regarding their ability to speak to the CGT decision-making process, (3) representation of an organization managing at least 500,000 covered lives, and (4) primary responsibility for medical or combined medical and pharmacy benefit adjudication. Participants representing pharmacy benefit-only roles or organizations with fewer than 500,000 covered lives were excluded.

A target sample of 20 payer leaders was established a priori to ensure representation across key US payer segments. Accordingly, the sample size was based on a recruitment target rather than thematic saturation. The sample was stratified to reflect a targeted cross-section of the US payer market, including national commercial health plans, regional commercial health plans, managed Medicaid and Medicare plans, and IDNs. The number of refusals was not recorded; no participants dropped out after enrollment.

Data collection

Interviews were conducted by telephone or audio-only videoconference and lasted approximately 60 min. Only the interviewer, the participant, and a non-speaking note-taker were present during the interview. No repeat interviews were conducted.

Interviews followed a discussion guide developed for the study. The guide included standardized prompts and was reviewed by the research team before use. Core topics included payer perspectives on CGT, including their overall perceptions of these therapies, the key challenges they face, and how they approach coverage and formulary decision-making. Other topics included utilization management strategies, financial risk considerations, value-based contracting (VBC), and emerging payment models. Interviews also explored how payers evaluate provider networks and their views on expanding CGT administration beyond academic medical centers. Questions were tailored as needed based on participant role while maintaining consistent coverage of core topics across interviews.

Data management and analysis

The research vendor conducted thematic qualitative analysis to identify recurring themes, subthemes, and areas of consensus or divergence across participants. Two researchers from the vendor independently coded the interview data. Any coding discrepancies were reviewed and resolved through discussion and consensus. The initial coding frame was organized around the core topics of the discussion guide. Additional subthemes were identified inductively during analysis to capture recurring or unexpected perspectives raised by participants.

Microsoft Excel was used to manage the qualitative coding process, including organization of coded transcript excerpts, tracking of themes and subthemes across participants, and comparison of findings by participant characteristics and payer type. Likert-scale items were summarized descriptively to identify areas of relative agreement, disagreement, or variation across participants. Additionally, analyses stratified by payer type were descriptive and exploratory in nature. No formal inferential comparisons were conducted across payer subgroups because sample sizes were small ($n = 2$–8) and the study was not designed to evaluate differences between payer segments.

Results

A total of 20 payer decision-makers were interviewed for this study, representing a diverse range of health plan types and organizational sizes. Interviews included open-ended discussion as well as structured rating and ranking exercises. Not all participants responded to every item; therefore, response counts varied across selected measures and are reported in the corresponding data tables.

Most participants held senior clinical or pharmacy leadership roles, with 15 (75%) serving as pharmacy directors or medical directors (Table 1). The remaining participants held executive leadership positions, such as executive director, vice president of pharmacy, and chief medical officer, all of whom were directly involved in coverage and reimbursement decisions for CGTs.

Collectively, the sample cohort included representatives from several large national and regional health plans (Table 1). Among interviewed payers, 8 represented health plans covering more than 15 million lives, 5 were from plans covering between 5 and 15 million lives, and 7 worked for plans covering between 0.5 and 5 million lives. Commercial health plans comprised the largest share of participants, accounting for 14 (70%) of the payer decision-makers interviewed. This cohort included 7 participants from national commercial plans and 7 from regional commercial plans. Managed Medicare and Medicaid plans accounted for 4 interviewees (20%), while IDNs were represented by 2 participants (10%).

Confidence and preparedness

Payers generally expressed confidence in both the safety and efficacy profiles of CGTs (Table 2). Across all 20 interviews, 18 participants (90%) indicated general or strong agreement that CGTs are safe. Views on efficacy were also favorable, though slightly less consistent, with 16 payers (80%) in agreement that CGTs are efficacious.

Table 1. Participant profile.

Characteristic	*n* (%)
Roles/positions	
Pharmacy leadership	11 (55)
Medical leadership	4 (20)
Executive leadership	5 (25)
Plan type	
National commercial plan	7 (35)
Regional commercial plan	7 (35)
Integrated delivery network	2 (10)
Medicare/Medicaid managed care plan	4 (20)
Size of health plan	
0.5–5 million lives	7 (35)
5–15 million lives	5 (25)
>15 million lives	8 (40)

$N = 20$.

Table 2. Perspectives on CGT clinical value and ecosystems.

Statements	Number of responses,[a] *N*	Strongly agree *n* (%)	Generally agree *n* (%)	Generally disagree *n* (%)	Strongly disagree *n* (%)
CGTs are efficacious	20	2 (10)	14 (70)	4 (20)	0 (0)
CGTs are safe	20	5 (25)	13 (65)	2 (10)	0 (0)
When thinking about innovations in healthcare, CGTs are among the most important medical innovations of our time	19	6 (32)	11 (58)	2 (10)	0 (0)
The current US healthcare system is incompatible with CGTs	19	13 (69)	5 (26)	1 (5)	0 (0)

Abbreviations. CGT, cell and gene therapy; US, United States.
[a]One participant did not complete the study due to time limitations.

Table 3. Challenges for CGT reimbursement (1 = most challenging).

Reimbursement challenges	Number of responses, N	Median[a]	Range[a]	Frequency of #1 rankings	Frequency of #2 rankings	Frequency of #3 rankings	% ranked in top 3[b]
High cost	19	1	1–4	12	5	1	95%
Uncertainty with long-term benefits	19	2	1–4	6	10	1	89%
Member portability risk	18	3	2–4	0	3	10	68%
Lack of innovative payment models	18	4	1–4	1	1	6	42%

$N = 19$.
One participant did not complete the study due to time limitations.
Abbreviation. CGT, cell and gene therapy.
[a]Median rank and range were calculated using available responses for each challenge.
[b]Percentages represent the proportion of participants who completed the ranking exercise ($N = 19$) and ranked each strategy among their top 3 priorities.

When considering medical innovation more broadly, 17 of 19 interviewed payers (89%) indicated general or strong agreement that CGTs represent some of the most important advances in modern medicine. Participants frequently characterized CGTs as transformative relative to historical treatment standards and recognized the meaningful clinical outcomes and progress observed with CGTs compared with prior standards of care.

At the same time, payers expressed broad agreement that the current healthcare landscape is poorly suited to accommodate CGTs. Eighteen of 19 participants (95%) noted general or strong agreement that the current US healthcare system is incompatible with the financial and operational demands of these therapies (Table 2). Payers cited misalignment between one-time, high-cost treatments and traditional insurance models designed around chronic treatment and recurring expenditures. As one national health plan payer noted, "We need better ways to pay for these therapies. Our healthcare system cannot support very expensive therapies, especially in the near future." Participants emphasized that, although CGTs may offer substantial long-term value, existing mechanisms are not designed to ensure that value is easily realized or widely distributed.

Top challenges to CGT reimbursement

Among 19 payers who ranked 4 predefined high-level challenges that complicate CGT reimbursement within their respective organizations, high upfront cost and uncertainty regarding long-term benefit emerged as the most significant challenges (Table 3). High cost was consistently ranked as the top barrier, achieving a median rank of 1 and ranking among the top 3 challenges for 18 payers (95%), including 12 who identified it as their highest priority. Payers highlighted concerns around the substantial one-time financial exposure associated with CGTs at the time of treatment, as reflected in one regional health plan payer's observation: "High cost is the big one, but it's more that it's a high upfront cost. Oncology therapies are also high cost, but it's spread out over 12 months."

Uncertainty surrounding long-term durability and clinical benefit was also highly prioritized, with a median rank of 2 and 17 payers (89%) ranking it among their top 3 challenges. Payers expressed ongoing concern regarding the durability of CGTs, with limited long-term evidence and lack of consensus on how durability should be defined and assessed. Payers acknowledged that, in the absence of extended follow-up, it is difficult to determine whether observed benefit will be sustained or whether retreatment or additional interventions may be required over time. This concern was reflected in the comments of one regional health plan payer who noted: "We want to see data that assures us that the money we're spending is for a curative treatment, and that patients don't relapse or need additional treatments." Durability concerns were especially relevant for therapies approved on the basis of shorter-term data or surrogate endpoints. Evidence generation was identified as a key factor in improving payer confidence.

Financial risk mitigation strategies

Among 19 payers who ranked potential strategies based on perceived feasibility and preference for managing financial exposure associated with CGTs, models that spread or transfer risk were most

Table 4. Payer-preferred strategies for managing the financial impact of CGTs (1 = most favorable).

Financial management strategy	Number of responses, N	Median rank[a]	Range[a]	Frequency of #1 rankings	Frequency of #2 rankings	Frequency of #3 rankings	% ranked in top 3[b]
Reinsurance or stop-loss	16	2	1–11	5	5	2	63%
Risk pools	13	3	1–9	5	1	2	42%
Warranty	15	3	2–12	0	5	3	42%
Exclude CGTs from coverage	14	3.5	1–12	3	2	2	37%
Restricting the number of providers in the CGT treatment network	13	4	1–12	2	2	1	26%
OBAs	13	4	1–11	3	0	2	26%
Amortization or installment payment plans	13	5	2–12	0	1	2	16%
Traditional fee-for-service payment model	10	8.5	3–12	0	0	2	11%
Combination of amortization with OBA	11	5	2–12	0	2	0	11%
Shifting coverage from medical to pharmacy benefit	11	10	3–12	0	0	2	11%
Subscription model	10	7.5	4–12	0	0	0	0%
Patient payment plans	9	9	4–12	0	0	0	0%

$N = 19$. One participant did not complete the study due to time limitations.
Abbreviations. CGT, cell and gene therapy; OBA(s), outcomes-based agreement(s).
[a]Median ranks were calculated using available responses for each strategy.
[b]Percentages represent the proportion of participants who completed the ranking exercise ($N = 19$) and ranked each strategy among their top 3 priorities.

frequently favored (Table 4). Reinsurance or stop-loss coverage emerged as the most preferred mitigation strategy, with a median rank of 2. Five payers ranked it as their first-choice strategy, and an additional 5 ranked it second, with 12 payers (63%) overall including it among their top 3 preferred payment models. This strategy was most commonly cited as a primary approach for managing high-cost CGT exposure among smaller health plans and employers.

Risk pools were also among the most frequently supported strategies, with a median rank of 3. Five participants identified risk pools as their most preferred risk mitigation strategy, and 8 participants (42%) ranked the approach among their top 3 preferred strategies. Payers described pooled risk arrangements as conceptually attractive, particularly for spreading the financial burden of rare, high-cost therapies across multiple payers. However, commercial payers emphasized practical implementation challenges, including coordinating participation across plans, navigating regulatory requirements, addressing potential antitrust or collusion concerns, and securing sufficient participation to meaningfully spread risk. As one regional health plan payer noted "[Risk pools] wouldn't be easy to implement. It would take multiple payers to work for commercial plans. You would almost have to get everyone in it."

Warranty models demonstrated similar levels of support. Warranty-based models were selected among the top 3 by 8 participants (42%; median rank 3), driven primarily by second- and third-place rankings, suggesting broad but less strongly prioritized interest.

Coverage-limiting strategies received moderate support. Excluding CGTs from formulary coverage was selected among the top 3 by 7 participants (37%; median rank 3.5), indicating that a subset of payers viewed therapy exclusion as a potential mechanism for limiting financial exposure.

OBAs were less prioritized, with a median rank of 4 and 5 participants (26%) placing it among their top 3 strategies. While many payers viewed these arrangements as a mechanism for aligning payment with realized clinical benefit, they were less frequently favored compared to more traditional risk-mitigation strategies, often due to perceived operational and implementation challenges. Restricting the number of providers in the CGT treatment network demonstrated comparable prioritization with 5 participants (26%) ranking it in their top 3 (median rank 4), indicating moderate but not universal support for network-based access controls.

Amortization-based models were also less favored overall, with only 3 participants (16%) ranking standalone installment payment models in their top 3 choices (median rank 5) and 2 participants (11%) ranking hybrid models combining amortization with OBAs in their top 3 (median rank 5). Payers noted that pay-over-time strategies may be more relevant for smaller health plans that face greater exposure to high-cost therapies.

The lowest-ranked strategies included traditional fee-for-service models and shifting coverage from medical to pharmacy benefit (white bagging), each of which was ranked as the third most preferred option by only 2 participants (11%) and neither of which was selected as a first- or second-choice

strategy (median ranks 8.5 and 10, respectively). Although participants did not view white bagging as one of the more effective strategies for protecting against financial exposure, they noted that specialty pharmacy can serve as a practical channel for product procurement and delivery. Subscription-based models (median rank 7.5), and patient payment plans (median rank 9) were not ranked among the top 3 options by any participant.

Strategies for managing the financial impact of CGTs varied substantially by payer type, often corresponding to differences in financial capacity, administrative infrastructure, and risk tolerance. National commercial health plans described a larger portfolio of mitigation strategies, most commonly including reinsurance or stop-loss, risk pools, and site-of-care management. However, participants from the largest national plans noted that their scale and financial capacity often allowed them to absorb the high-cost impact of CGTs without relying heavily on additional risk-mitigation mechanisms. National plans also reported restricting CGT administration to designated centers of excellence (COEs) to more efficiently manage utilization and reduce variability in administrative and procurement costs. Regional commercial plans emphasized more conservative strategies and generally noted more sensitivity to high one-time CGT costs. Participants from regional plans reported prioritizing reinsurance or stop-loss coverage, particularly among plans covering 0.5–5 million lives. Typical stop-loss arrangements were described as involving per-member, per-month fees and high deductibles, often over 1 million dollars per episode. Risk pools, OBAs, and amortization were also viewed as appealing in principle, but less frequently implemented due to administrative burden and uncertainty regarding long-term member retention. Regional payers indicated that longer installment periods, often exceeding 3 to 5 years, would be required for amortization models to meaningfully reduce financial exposure. While formulary exclusion of CGTs was described as less common, regional plans noted that it remains a possible option under conditions of extreme financial strain.

Managed Medicare, Medicaid, and IDNs reported distinct mitigation strategies driven by higher baseline risk exposure and longer member retention. These payers more frequently cited interest in risk pools, reinsurance or stop-loss coverage, amortization, and warranty-based arrangements. Some participants expressed interest in state or federally supported risk pools for CGTs, analogous to existing Medicare dialysis or transplant risk-sharing models. Participants emphasized that legal and regulatory uncertainties, including limitations on data sharing between risk pool participants, remain a constraint on increased adoption.

Value-based contracting

Payers generally viewed VBC or OBAs for CGTs as a potentially useful but operationally challenging reimbursement approach. While many payers acknowledged that VBCs could help mitigate the financial risk associated with high upfront therapy costs, significant barriers to negotiation and execution were noted. A recurring concern was limited manufacturer willingness to engage in meaningful risk-sharing arrangements, particularly for rare diseases with small patient populations. Payers also emphasized the lack of consensus around clinically meaningful outcome measures and highlighted difficulty aligning on endpoints that are broadly accepted across stakeholders, a challenge reflected in one national health plan payer's comment: "We don't have value-based contracts because we can't agree upon the metric to be measured."

Commonly cited operational challenges for VBCs included difficulties in establishing systems to track patient outcomes, especially in the context of long-term follow-up and member portability. Regional payers, in particular, reported limited infrastructure and resources to support longitudinal data collection. Contract timelines were another important factor, as payers expressed reluctance to commit to multi-year arrangements exceeding typical member enrollment durations. In addition, payers indicated that negotiating the extent of financial concessions can be challenging, with rebate levels sometimes falling short of fully offsetting financial risk.

Despite these challenges, payers reported somewhat positive impressions of VBCs. Twelve of 20 payers (60%) indicated that VBCs and OBAs could be feasible and may help mitigate financial exposure under appropriate conditions. Regional and national payers noted growing internal familiarity with VBC frameworks but emphasized that successful implementation depends on contracts that rely on

Table 5. Ranked barriers for innovative payment model adoption (1 = most significant barrier).

Adoption barrier	Number of responses, N	Median rank[a]	Range[a]	Frequency of #1 rankings	Frequency of #2 rankings	Frequency of #3 rankings	% ranked in top 3[b]
Member portability	18	2	1–6	6	5	4	79%
Ability to track patients over long-term	17	2	1–6	5	7	2	74%
Inconsistent access to data	17	3	1–5	2	3	8	68%
Uncertain patient volume	17	4	1–6	2	1	3	32%
Exclusion of CGT from formularies	17	5	1–6	3	2	0	26%
Antiquated medical billing systems	16	4.5	1–6	1	1	1	16%

$N = 19$. One participant did not complete the study due to time limitations.
Abbreviation. CGT, cell and gene therapy.
[a]Median ranks are calculated using available responses for each barrier.
[b]Percentages represent the proportion of participants who completed the ranking exercise ($N = 19$) and ranked each strategy among their top 3 priorities.

straightforward and binary outcome measures that are easy to assess and operationalize. Payers noted that increasing market competition and the approval of additional therapies could improve manufacturer flexibility for different value-based arrangements over time. One regional health plan payer noted "I think we're starting to see more willingness to engage in those outcomes-based, risk-sharing agreements and actually having discussions regarding actually effective VBCs that would help equally the payers and the manufacturers."

Barriers to innovative payment models

Among 19 payers who ranked barriers to implementing innovative payment models for CGTs, participants most consistently prioritized challenges related to member portability, long-term patient tracking, and inconsistent access to outcomes data (Table 5). Member portability and the ability to track patients over extended periods of time were the most frequently identified barriers, with 15 payers (79%) and 14 payers (74%), respectively, ranking them among their top 3 challenges. Participants highlighted the difficulty of maintaining longitudinal follow-up in the absence of standardized infrastructure, as well as the challenge of aligning payment with long-term clinical value given the risk of member turnover between health plans. These concerns were most evident among commercial payers, where average member retention was reported to range from approximately 1–3 years. Managed Medicare and Medicaid payers reported modestly longer retention periods of 2–5 years. IDNs described substantially longer average member enrollment durations, often extending 5–10 years with comparatively lower portability-related risk.

Inconsistent access to data was also frequently identified as a barrier to implementing innovative payment models, ranking among the top 3 barriers for 13 payers (68%). Many participants cited significant variability in data availability and completeness across different CGTs. As one regional health plan payer noted, "Inconsistent access to data is number one… This goes along with problems tracking patients over the long term. We need data and [we] need to be able to continually track it."

Coverage and utilization

When evaluating CGTs for coverage, all 20 payers (100%) cited clinical trial inclusion and exclusion criteria as a basis for decision-making (Table 6). Approved FDA labeling was cited by 15 participants (75%) as a key determinant of coverage criteria, while other, less frequently referenced sources included clinical guidelines ($n = 4$; 20%), peer-reviewed publications ($n = 4$; 20%), key opinion leader input ($n = 2$; 10%), manufacturer-provided information ($n = 2$; 10%), disease epidemiology ($n = 1$; 5%), budget impact analyses ($n = 1$; 5%), and input from patient advisory groups and treatment sites ($n = 1$; 5%). Compared to government-sponsored plans, commercial payers reported applying prior authorization (PA) requirements for CGTs that were typically more restrictive than FDA labeling and closely aligned with clinical trial inclusion and exclusion criteria. These requirements were commonly reported to include confirmation of disease severity, prior treatment history, prescriber qualifications, and treatment center accreditation.

Table 6. Primary source data used for formulary and coverage decisions.

Source data	*n* (%)
Clinical trial inclusion/exclusion criteria	20 (100)
Approved FDA label	15 (75)
Clinical guidelines	4 (20)
Peer-reviewed publications	4 (20)
KOL input	2 (10)
Information from manufacturer	2 (10)
Disease epidemiology	1 (5)
Budget impact analyses	1 (5)
Input from PAGs and treatment sites	1 (5)

$N = 20$.
Abbreviations. FDA, U.S. Food and Drug Administration; KOL, key opinion leader; PAGs, patient advisory groups.

Payers noted that limited data transparency can make it more difficult to achieve streamlined coverage and reimbursement for CGTs. Participants expressed a preference for having comprehensive access to detailed treatment-level documentation, including clinical notes, to support coverage evaluations. Half of interviewed payers described these dynamics as challenging and shared that authorization timelines and risk of denial may increase when visibility to these data is limited.

Provider networks and community expansion

Payers expressed a range of views regarding the expansion of CGT administration to community treatment settings. When asked whether expansion of CGT administration into community hospitals and practices is necessary to ensure broader patient access, 8 of 17 payers (47%) indicated that expansion to community hospitals is necessary to support broader patient access, 5 (29%) expressed that expansion may be appropriate with sufficient safety protocols in place, and 4 (24%) indicated that such expansion is unnecessary.

Payers who supported expansion to community treatment settings commonly cited the potential to increase access to care and accommodate future growth in CGT utilization. One regional health plan participant noted, "Right now, treatment is localized and takes place at academic centers because they do the research, but just like cancer care now, once it spreads to more community centers, access will be much better." These participants observed that increasing treatment volumes and expanding CGT indications may place greater demand on existing delivery networks. However, support for expansion was typically contingent on the ability of the community sites to demonstrate adequate infrastructure, specialist oversight, and operational readiness. In addition, many payers noted that growing clinical experience with CGTs, particularly chimeric antigen receptor (CAR) T-cell therapies, has improved familiarity with toxicity management and escalation pathways, which could facilitate administration in a broader range of settings when appropriate safeguards are in place.

In contrast, payers who viewed expansion as unnecessary cited the adequacy of existing access mechanisms, including referral networks and patient travel support programs that allow patients to receive CGTs at established COEs. One managed Medicaid plan participant noted, "If you live in a rural area and it's a long drive, we'll find housing for the patient or their family to get these therapies. There are mechanisms in place." These participants emphasized the benefits of centralized administration, including greater control over treatment volume, standardized care pathways, and reduced financial and operational risk.

Discussion

This qualitative study provides insight into how US payer decision-makers are currently approaching CGT reimbursement and financial risk management across a mix of commercial, governmental, and IDN settings. Overall, payers expressed confidence in the clinical importance of CGTs and recognized their potential to deliver meaningful clinical benefit in serious diseases. However, payer enthusiasm was tempered by concerns about upfront costs, limited long-term evidence at the time of launch, administrative complexity, and the need for effective financial risk-mitigation models.

Consistent with prior research, payers in our study frequently identified stop-loss insurance or reinsurance as a preferred financial risk-mitigation strategy for CGTs[12]. Stop-loss is widely utilized across the commercial insurance market landscape to protect against financial exposure of high-cost therapies, with approximately 74% of private-sector workers in self-insured plans estimated to be covered by such arrangements[13]. However, available data do not indicate whether, or to what extent, these insurance products are specifically designed to address CGT-related financial risk, and their application to CGTs remains an area of ongoing discussion. Under stop-loss or reinsurance arrangements, payers or plan sponsors purchase coverage from third-party insurers to mitigate volatility and offset catastrophic exposure from high-cost claims that exceed specific dollar thresholds[9,13]. Reinsurance serves as secondary insurance for insurers, whereas stop-loss coverage provides protection for self-funded plan sponsors. However, several factors may influence how effectively stop-loss coverage addresses CGT-related financial risk. Stop-loss insurance products are typically designed to protect plan sponsors against rare and unexpected events, such as sepsis management or neonatal intensive care[14,15]. In contrast, CGTs target identifiable patient populations with known diagnoses (e.g. hemophilia or sickle cell disease), potentially rendering associated costs and claims as more predictable at the individual patient level. Stop-loss carriers may often underwrite risk and may even respond to expected CGT exposure by raising premiums, narrowing CGT coverage terms, or even "lasering out" or excluding specific high-risk members[14,15]. Ultimately, these dynamics suggest that although stop-loss and reinsurance remain important components of payer risk management strategies for high-cost therapies, the unique clinical and financial characteristics of CGTs may influence how these payments are structured and applied in practice.

Risk pools were also ranked favorably by interviewed payers and may be conceptually better aligned with several CGT-specific challenges, including high upfront cost, small eligible populations, and member portability. By decoupling payment responsibility from a CGT user's plan enrollment duration, pooled models offer the opportunity to mitigate portability risk when members transfer to a different payer within the same risk pool[9]. This may be particularly relevant for CGTs as commercial payers in our study reported an average member retention of approximately 1 to 3 years, whereas the potential clinical and economic benefit of treatment may extend over a much longer period of time. However, despite conceptual support, payers expressed skepticism regarding implementation. Commercial payers highlighted barriers that limit feasibility, including regulatory constraints and the absence of a coordinating authority to operationalize multi-payer pooling arrangements. These findings indicate that while risk pooling strategies for CGTs may be viewed favorably by payers, governance, regulatory requirements, and operational feasibility remain important factors that may influence the scalability of these arrangements in practice.

Notably, all participants in this study cited clinical trial inclusion and exclusion criteria as an important basis for coverage decision-making. Commercial payers in particular reported that PA criteria were often more restrictive than FDA labeling and closely tied to clinical trial eligibility requirements. This approach reflects payer interest in aligning treatment access with clinical evidence; however, it may also create uncertainty when trial populations do not fully represent patients who may be considered for treatment in real-world practice. This potential gap between FDA-labeled eligibility and plan-specific coverage requirements has been documented across commercial CGT coverage policies. In an analysis of 532 commercial health plan coverage policies for FDA-approved CGTs, Chambers et al. found that 276 policies (52%) included criteria requirements beyond FDA labeling[16]. Among the 251 policies with additional patient subgroup requirements, 220 (88%) used criteria that were consistent with or similar to pivotal-trial eligibility requirements, including 161 policies (64%) that were either fully consistent with trial criteria or more stringent. Ultimately, these findings suggest that pivotal-trial eligibility criteria play an important role in how commercial payers operationalize coverage requirements for CGTs. Reliance on trial eligibility criteria may help support consistency between coverage decisions and the evidence available at the time of review, particularly when post-approval clinical data remain limited. As real-world experience continues to accumulate and long-term follow-up data become better characterized, understanding how emerging evidence informs coverage policy and utilization management requirements will be an important area for future evaluation.

Payers also viewed OBAs and VBCs as potentially useful but operationally challenging. Over half of participants indicated that VBCs could be feasible for CGTs, particularly when endpoints are

straightforward, clinically meaningful, and measurable over time. Notably, publicly available data indicate that outcomes-based contracting and other performance-linked payment arrangements for CGTs remain relatively uncommon, with only 15 identified agreements across 10 approved CGTs[10]. While the reasons for the limited uptake of CGT OBAs are likely multifactorial, participants in our current study identified several important implementation challenges that may contribute to their limited adoption, including limited infrastructure for long-term outcomes tracking, uncertainty regarding endpoint selection, administrative burden, and concerns related to member portability and health plan turnover. Additional experience with OBA design, implementation, and evaluation may provide greater insight into the feasibility and effectiveness of these models in managing the clinical and financial uncertainties associated with CGTs.

As CGT utilization continues to grow, participants expressed differing views regarding whether administration should expand into community-based settings. Among 17 participants who commented on this topic, 47% indicated that expansion to community hospitals is necessary to support broader patient access, 29% indicated that expansion may be appropriate when sufficient safety protocols are in place, and 24% viewed such expansion as unnecessary. Participants who supported expansion cited the need to improve access, accommodate anticipated growth in utilization, and reduce reliance on academic medical centers. These findings are consistent with emerging clinical and real-world evidence demonstrating safe and effective CAR T-cell therapy delivery in select community and non-academic centers[17,18]. However, participants consistently emphasized that site readiness, specialist oversight, operational capabilities, toxicity management pathways, and continuity-of-care processes are important considerations for any expansion of administration beyond established academic centers. Participants who did not view expansion as necessary generally cited the adequacy of existing referral pathways and access-support mechanisms, as well as the perceived advantages of centralized administration. In their view, COEs already provide access to CGTs while concentrating clinical expertise, treatment volume, and operational resources within established networks. Overall, the findings highlight differing payer perspectives regarding the circumstances under which community-based CGT administration may be appropriate, with considerations related to clinical oversight, operational readiness, and safety management protocols identified as important factors when evaluating sites for CGT delivery. The relevance of these considerations may increase over time as CGT indications and treatment volume continue to expand.

Limitations

Certain limitations should be considered when interpreting the findings from this study. First, despite representation from several large national and regional plans, the sample size of 20 individual payer decision-makers may not fully reflect the full diversity of perspectives across the entire US payer landscape. Accordingly, findings from this study should be interpreted as exploratory. Second, the double-anonymized, semi-structured interview format relies on self-reported data, which may be subject to recall bias or social desirability bias related to perceptions of system preparedness. Selection bias is also possible, as recruitment through curated expert panels can favor more highly engaged or opinionated payer experts, and the inclusion of participants with high self-rated proficiency (e.g. 6–7 of 7) may further concentrate perspectives of more opinionated individuals. Third, perceptions of CGT safety, efficacy, and system preparedness reflect aggregated payer sentiment across heterogeneous cell and gene modalities and may not fully capture variation across specific therapies, indications, or care settings.

In addition, because this was a qualitative study, the rankings and other quantitative data provided by participants were intended to identify trends and consensus areas and were not powered or designed to detect differences between payer subgroups. Moreover, the ranking exercises were subject to partial completion, as not all participating payer decision-makers ranked every item presented, despite having the opportunity to rank the full set of response options. This incomplete response pattern may introduce bias into the ranking results, as the relative prioritization of unranked items cannot be determined.

Lastly, this study did not collect contract-level data on the adoption, duration, or design of financial risk mitigation arrangements, nor did it assess claims, outcomes, financial performance, or impact on patient access associated with individual models. Results therefore only reflect participant-reported

perspectives and preferences at the time of interview. Future studies using available payer, employer, and manufacturer contract data may be needed to assess uptake and outcomes across financing strategies and to provide more granular insight across specific CGT modalities.

Conclusions

This study provides a focused assessment of US payer perspectives on the evolving landscape of CGT reimbursement and financial risk management. While payers recognize the clinical potential of CGTs, persistent concerns regarding high upfront costs, long-term durability, and operational challenges continue to shape coverage strategies and the adoption of innovative payment models. As the CGT field continues to expand, ongoing evaluation of reimbursement frameworks will be important to understand how coverage strategies and financing models evolve in practice. Future research examining the impact of long-term clinical outcomes, policy changes, and real-world implementation experience may help better characterize the feasibility of novel payment mechanisms and their role in supporting CGT financing and reimbursement.

Transparency

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Declaration of financial/other relationships

Both authors are employed by McKesson. JD has leadership and fiduciary roles at Taxis Pharmaceuticals and Valorum Biologics.

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Author contributions

The authors meet criteria for authorship as recommended by the International Committee of Medical Journal Editors (ICMJE) based on substantial contribution to the conception and design of this study, and analysis and interpretation of the data. ECP was responsible for the drafting and revising of the manuscript. Both authors were responsible for supervision of the study, critical review of the manuscript, and final approval of the version to be published. Both authors agree to be accountable for all aspects of the work.

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Previous presentations

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ORCID

Elias C. Pittos http://orcid.org/0009-0005-3593-5740
Joe DePinto http://orcid.org/0009-0007-2378-7626

Data availability statement

Data available on request from the authors.

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