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BACKGROUND

- Cell and gene therapies (CGTs) are an emerging class of medicines holding immense promise for addressing a variety of diseases
- The rapid pace of development and the novel nature of these treatments create significant hurdles for coverage, reimbursement, and cost management
- The unique financial and logistical challenges of CGTs, including high upfront cost density and the need for long-term outcomes tracking, demand innovative approaches that reconcile short-term budget impact with long-term value realization
- There is a clear and urgent need for new frameworks that support effective integration of CGTs into managed care and enable greater patient access

OBJECTIVES

- To gather payer perspectives on coverage, cost management, and reimbursement models for CGT
- To identify key challenges and strategies for successful CGT access and integration

METHODS

- Key CGT decision-makers from US payer organizations were selected as participants
- Semi-structured, double-blind interviews were held from February to March 2025
- Interviews were 45-60 minutes and included quantitative Likert scale ratings and open-ended qualitative feedback
- Topics included CGT access challenges, value and reimbursement, coverage strategies, and provider network design
- Data were anonymized and analyzed to identify key trends and consensus areas

CONCLUSIONS

- While payers recognize the transformative potential of CGTs, their readiness to integrate them into managed care remains constrained by significant product cost density and the uncertainty surrounding durability of benefit
- As therapies demonstrating multi-year durability become increasingly available, considerations around long-term efficacy and sustained benefit will play a critical role in shaping delivery strategies and access frameworks
- Future access solutions will hinge on advancing safe and effective CGT administration while thoughtfully assessing the role of community-based delivery to enhance patient reach
- Clear, clinically relevant, and measurable outcomes are essential to demonstrate the value of innovative payment models and ensure long-term patient monitoring
- The path forward will be shaped by the ability to design reimbursement and payment models that are both innovative and sustainable

Characteristics

- A total of 20 payer representatives participated, all of whom held leadership roles within their organizations (Table 1)
- Most of the interviewees represented commercial health plans. Collectively, the interviewed payer organizations represent approximately 280 million covered lives (Table 1)

Characteristic Roles/Positions Pharmacy leadership Medical leadership Plan Type National commercial plan Regional commercial plan Integrated Delivery Network Medicare/Medicaid managed care plan Size of Health Plan 0.5M-5M lives 5M-15M lives >15M lives

Table 1. Participant Profile

Payer Outlook

 Payers expressed confidence in the clinical value of CGT, with 90% agreeing that CGTs are safe and 80% agreeing they are effective (Figure 1)

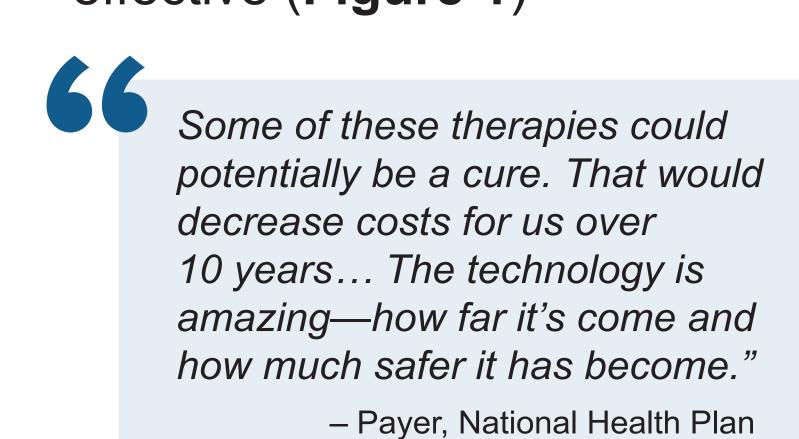
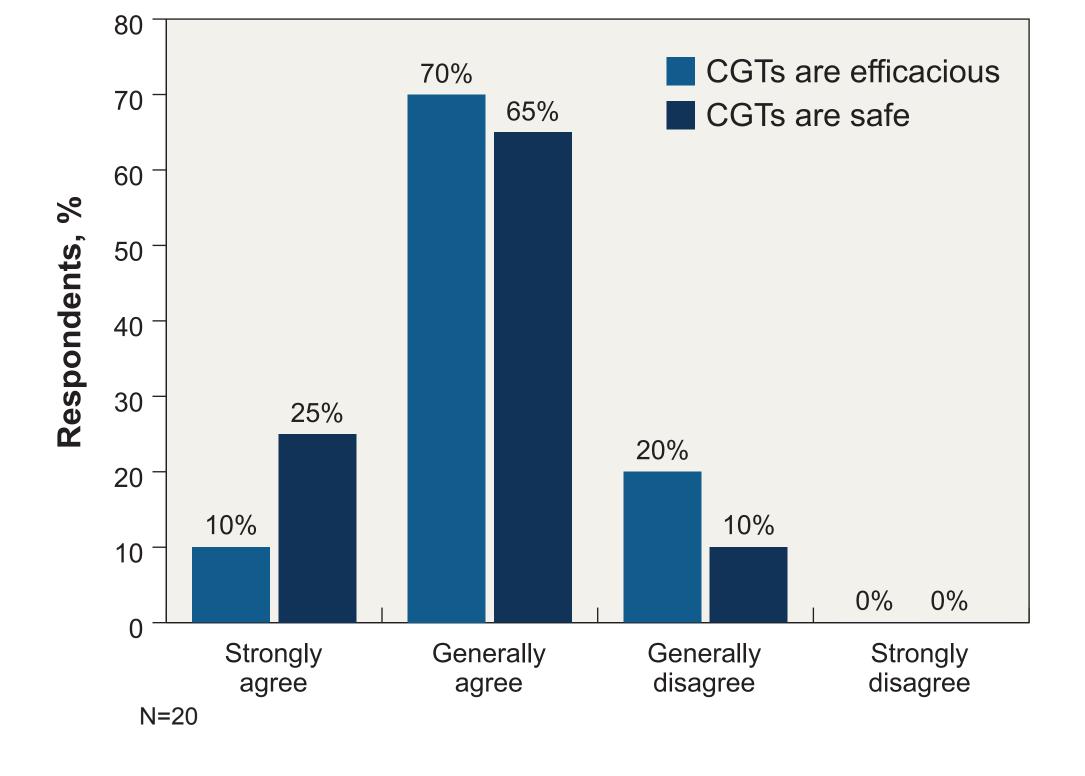


Figure 1. Payer Perspectives of CGT Efficacy



Preparedness

 Despite this overall confidence, 95% of payers agreed that the US healthcare system is not adequately prepared for broad CGT adoption (Figure 2)

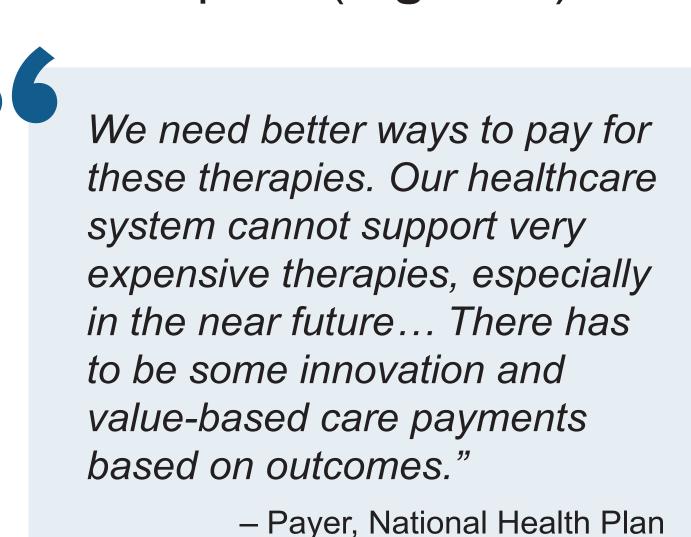
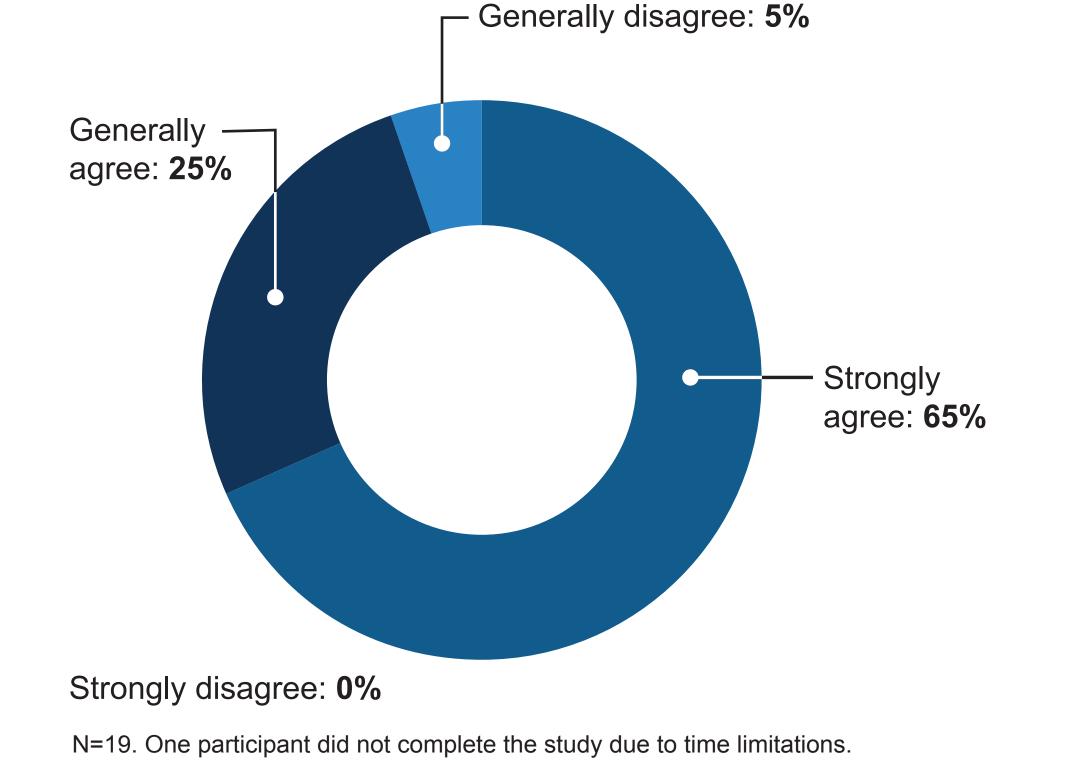


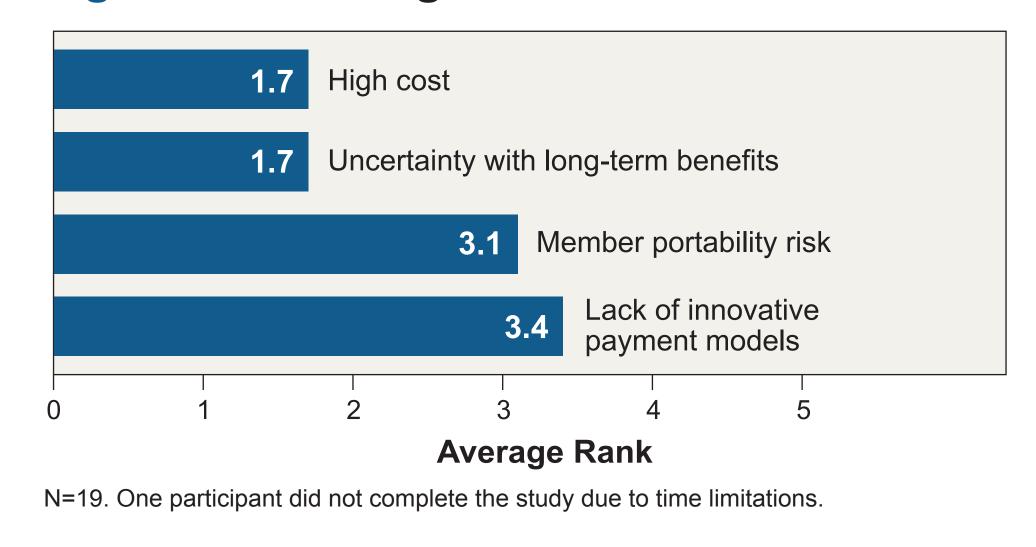
Figure 2. Payer Perspectives on Incompatibility of US Healthcare System and CGTs



Top Challenges

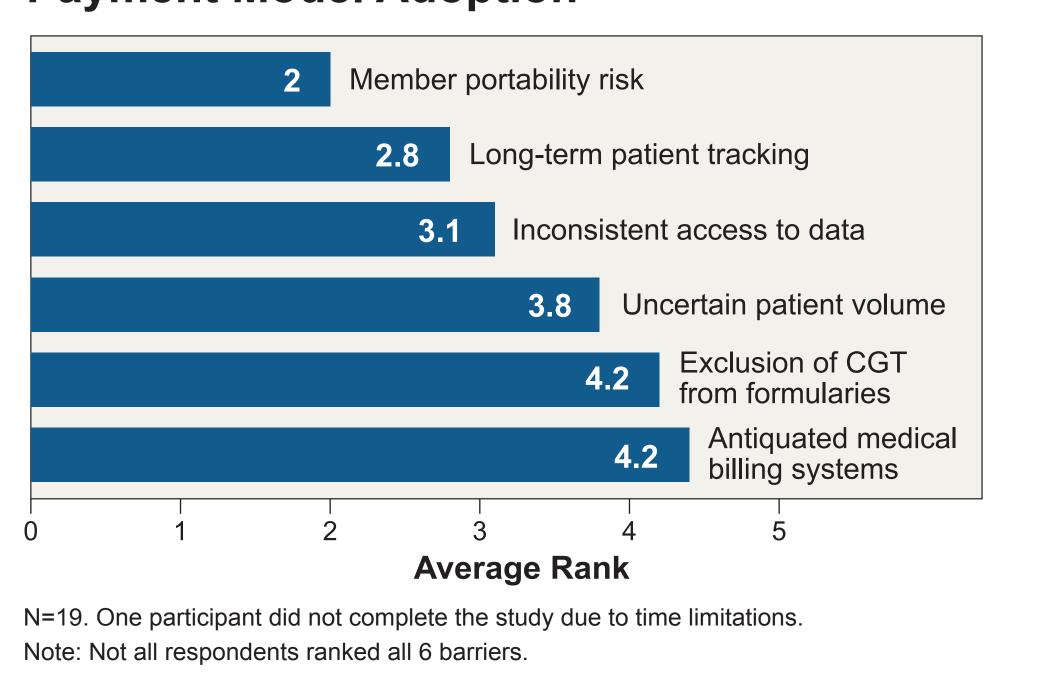
- High cost density and uncertainty about long-term benefits were the most cited challenges for CGT reimbursement (Figure 3)
- Respondents ranked member portability risk and difficulty of long-term patient tracking as the most significant barriers to implementing innovative payment models (Figure 4)
- Payers expressed a reluctance to finance a one-time, high-cost treatment when potential member turnover creates uncertainty around realizing long-term value
- Likewise, long-term follow-up requires persistent collection and reporting of patient data, which can be operationally complex and resource intensive
- Payers also emphasized the importance of clinically relevant and measurable endpoints to ensure that innovative payment models are both viable and sustainable

Figure 3. Challenges for CGT Reimbursement



RESULTS

Figure 4. Ranked Barriers for Innovative Payment Model Adoption



Provider Network Design

- Nearly half of payers agreed that expanding CGT administration into community hospitals is essential for improving patient access (Figure 7)
- They emphasized that community-based access is critical for reaching rural populations and meeting rising demand as CGT utilization grows
- Payers also noted that advancements in recognizing and managing CAR T-cell therapy side effects have made administration in community settings increasingly feasible
- However, some payers questioned the need for expansion beyond established Centers of Excellence, citing existing support mechanisms for patient travel and lodging as sufficient to ensure access

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."

Payer, Regional Health Plan

Coverage and Utilization

- Payers cited clinical trial inclusion and exclusion criteria and FDA labels as commonly used primary source data for formulary and coverage decisions (Figure 6)
- For commercially insured populations, payers reported that utilization management remains highly stringent, with prior authorization requirements typically aligned to clinical trial eligibility criteria over FDA labeling or clinical

Figure 6. Primary Source Data for Formulary and Coverage Decisions

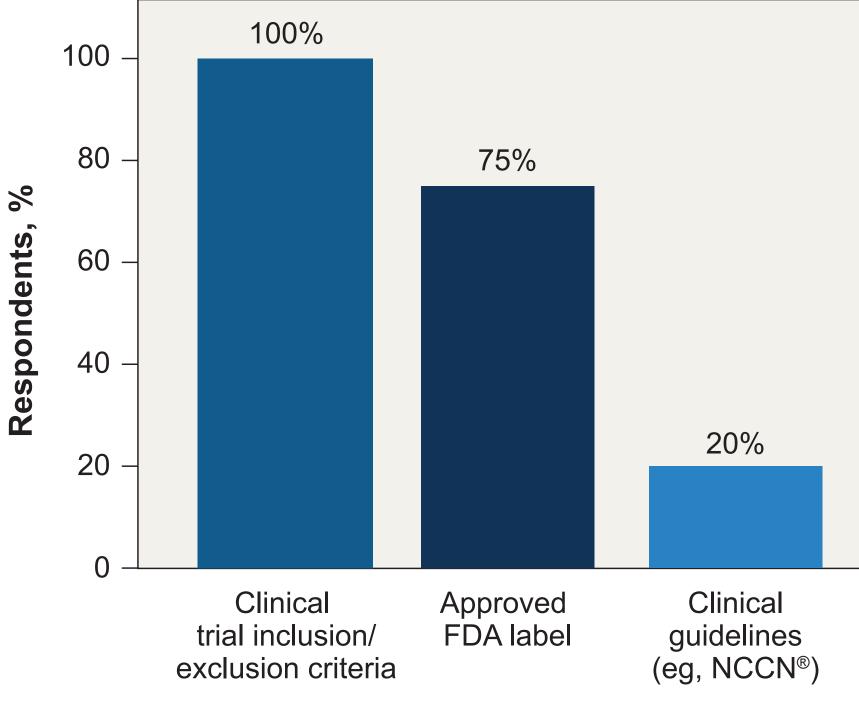
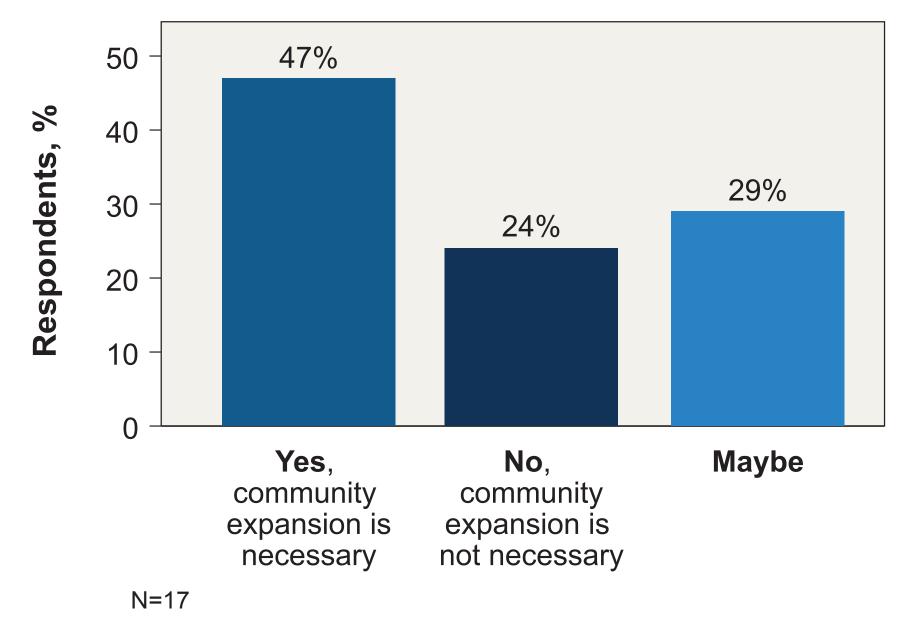


Figure 7. Perception on the Need for **CGT Expansion in Community Settings** to Sustain Access



I think that CGT should eventually expand to the community setting. And I feel that when you expand it to [community hospitals], then it'll definitely be utilized a lot more." Payer, Regional Health Plan



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Reimbursement Strategies

 To mitigate financial risk, payers ranked stop loss as the preferred strategy, especially among smaller health plans and employers, followed by risk pools and outcomes-based agreements (Figure 5)

We don't have value-based contracts because we can't agree upon the metric to be measured. We are a large enough company that we are able to pay upfront. It's a lot of effort to invest when, many times, we lose to the manufacturer." Payer, National Health Plan

Figure 5. Preferred Financial Risk Mitigation **Strategies** Reinsurance or stop loss

