ACCESS, REIMBURSEMENT, AND RISK MANAGEMENT CHALLENGES FOR CELL AND GENE THERAPIES: US PAYER PERSPECTIVES

POSTER #53

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BACKGROUND

- Cell and gene therapies (CGTs) offer substantial clinical potential and have demonstrated the ability to provide durable, potentially curative benefit in many patients with cancer, rare, or previously untreatable conditions[1]
- However, these innovative therapies present significant financial risk-management challenges for US healthcare payers
- High upfront acquisition costs, actuarial uncertainty regarding long-term durability, and a lack of standardized outcomes data create barriers for coverage and cost management of CGTs
- Optimizing financial sustainability is critical for timely patient access

OBJECTIVE

To evaluate US payer perspectives on reimbursement, access, and management strategies across CGTs.

METHODS

- Between February and March 2026, double-anonymized, semi-structured interviews were conducted with US payer leaders and decision-makers responsible for CGT coverage and reimbursement
  - Interviews (60 minutes) included quantitative Likert-scale assessments and open-ended questions for qualitative feedback
- Interview discussions focused on payer perspectives regarding CGT reimbursement dynamics, payment models, provider network design, channel economics, financial risk mitigation, and future CGT reimbursement trends
- De-identified interview findings were analyzed to identify recurring themes, consensus viewpoints, and emerging trends related to CGT reimbursement

CONCLUSIONS

- US payers continue to navigate significant reimbursement, contracting, and operational complexities associated with CGTs
- Provider experience, network design, and reimbursement structure emerged as recurring themes influencing both access and site-of-care decision-making
- Shared risk models generated mixed reactions among payers, reflecting continued interest in novel approaches to managing CGT financial risk alongside significant concerns regarding actuarial uncertainty, governance, and implementation complexity
- As the CGT landscape expands, sustainable access will increasingly depend on balancing innovation with reimbursement models and management strategies that can accommodate long-term clinical and financial uncertainty

References: 1. Pittos E and DePinto J. Five-year durability in cell and gene therapy: Evidence review and implications for payer coverage. *Expert Rev Pharmacoecon Outcomes Res*, 2026. In submission.

Abbreviations: CAR-T, chimeric antigen receptor T-cell; **CMS**, Centers for Medicare & Medicaid Services; **CoE**, center of excellence; **FACT**, Foundation for the Accreditation of Cellular Therapy; **HCPCS**, healthcare common procedure coding system; **IEC**, immune effector cell; **MCO**, managed care organization; **US**, United States.

DEMOGRAPHICS

The study included 35 payer leaders with expertise in CGT, collectively representing approximately 295 million (M) covered lives.

Table 1. Participant Characteristics

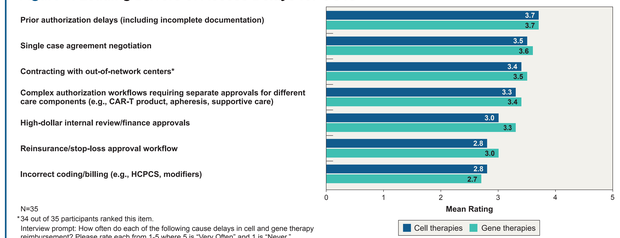
Roles/Positions	
Senior pharmacy leadership	18 (51%)
Medical officer or director roles	12 (34%)
Other leadership	5 (14%)
Health Plan Type	
National commercial	11 (31%)
Regional commercial	9 (26%)
National Medicare Advantage	4 (11%)
National Medicaid MCO	6 (17%)
State Medicaid MCO	4 (11%)
CMS	1 (3%)
Health Plan Size	
<1M covered lives	4 (11%)
1M-5M covered lives	13 (37%)
5M-15M covered lives	3 (9%)
>15M covered lives	15 (43%)

N=35

KEY FINDINGS

Payers identified prior authorization as the leading driver for access delay in both cell and gene therapies. Single case agreement (SCA) negotiation and out-of-network contracting were close behind.

Figure 1. Leading Drivers of Access Delays for CGTs



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*34 out of 35 participants ranked this item.
Interview prompt: How often do each of the following cause delays in cell and gene therapy reimbursement? Please rate each from 1-5 where 5 is "Very Often" and 1 is "Never."

> *If you [need] a* ***single case agreement****, that may take longer. If you* ***haven't worked with us…it's going to take a little bit longer****. For centers of excellence, it's not going to be an issue."*
>
> – Regional Commercial Plan

> *Gene therapy has* ***extended prior authorization, genetic confirmation review****.* ***Reinsurance*** *pre-clearance may take a long time.* ***Finance approval*** *because $2 million, $3 million is involved. […]* ***There is more friction in gene therapy…compared to CAR-T [therapy]****."*
>
> – Regional Commercial Plan

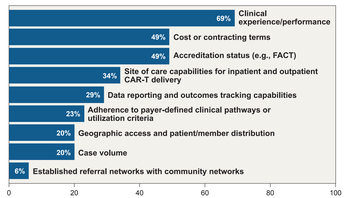
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RESULTS

Seventy-nine percent of payers reported using a CoE model for CGT delivery (data not shown). The most commonly cited driver for CoE network inclusion was clinical experience/performance.

> *I would say probably* ***clinical experience and performance [is the]*** *number one [priority]… clinical experience and performance go hand-in-hand with [case volume] because we can overlook case volume if they've got good clinical experience performance."*
>
> – National Commercial Plan

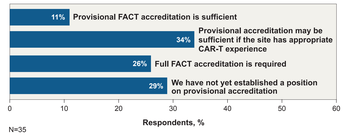
Figure 2. Drivers for Payer CoE Network Inclusion



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Interview prompt: Which factors are most important to your organization in determining a treatment site's CoE status for CAR-T? Select up to three.

Payers expressed mixed views regarding provisional FACT accreditation for community-based IEC therapy delivery, with some supporting it as an acceptable pathway and others favoring full FACT accreditation.

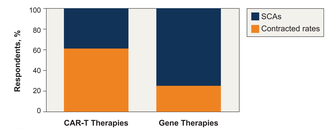
Figure 3. Payer Views on New Provisional FACT Accreditation Pathway for Community Setting



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Interview prompt: How do you anticipate your organization responding to new FACT standards recently published for IECs in the community setting, which offer a provisional accreditation pathway? Which of the following statements do you agree with?

Reimbursement strategies vary by therapy type. CAR-T therapies are more commonly reimbursed through contracted rates (61%), whereas gene therapies are predominantly reimbursed through SCAs (75%).

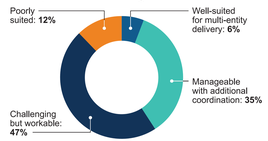
Figure 4. Payer-reported Reimbursement Approach



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Interview prompt: What would you estimate the breakdown of cell (CAR-T) and gene therapy claims resolved through contracted rates vs. SCAs within a year?

Many payers report challenges with current CAR-T therapy reimbursement models when care spans multiple care settings. More than half of respondents (59%) indicated that case-rate and bundled-payment models present challenges or are poorly suited when care is delivered across multiple entities.

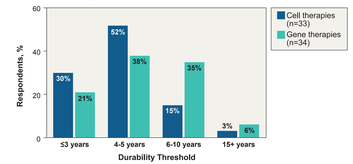
Figure 5. Payer Perspectives on Case Rates for CAR-T Therapy When Care Is Delivered Across Multiple Care Settings



N=34
Interview prompt: How well do current case-rate or bundled-payment strategies support CAR-T delivery when care is provided across multiple entities (e.g., apheresis site, community physician practice, and hospital)? Please select the most appropriate description.

Durability expectations differed by therapy type. Most payers considered 4-5 years of follow-up sufficient for cell therapy (52%), whereas expectations for gene therapy were longer, with 41% of payers citing durability thresholds of at least 6 years.

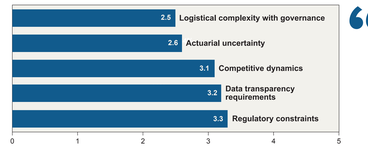
Figure 6. Expectation for Durable Benefit of CGTs



Interview prompt: For each modality, how long should a cell or gene therapy demonstrate sustained clinical benefit to be considered successful and to meaningfully alleviate concerns with long-term durability?

Payer sentiment toward shared risk models was mixed. Among surveyed payers, 36% viewed shared risk models (e.g., risk pools) favorably, while 46% were skeptical and 18% questioned their value altogether (data not shown). Logistical complexity and actuarial uncertainty emerged as the leading influential barriers to implementation (Figure 7). Smaller and regional plans were generally more receptive to these models than larger payers (data not shown).

Figure 7. Ranked Barriers for Shared Risk Model Adoption

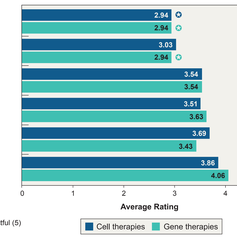


N=35
Interview prompt: Please rank the following factors from most influential (1) to least influential (5) as barriers preventing implementation and scaling of shared risk models for gene therapies.

> *[Risk pools] would be all about the numbers and the potential payments and over what period of time. I'm* ***not seeing the likelihood of various organizations actively competing coming together*** *and forming something like this [multi-payer risk pool]. So, it's a nice thought and I've heard of this before, but* ***I don't necessarily think that's a likely probability****."*
>
> – National Commercial Plan

National standards for CGT outcomes data collection ranked among the most impactful enablers of access, along with federal reinsurance/stop-loss programs and solutions to address member portability.

Figure 8. Drivers to Improve CGT Access and Reimbursement



N=35
Interview prompt: Please rank the following potential changes from most impactful (1) to least impactful (5) for improving cell and gene therapy access and reimbursement. Rank for cell therapies followed by gene therapies.

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