CTCS CELL THERAPY COMMERCIALIZATION SYMPOSIUM®

BREAKING BARRIERS TO CGT COMMERCIALIZATION:
Key Themes from the Inaugural Cell Therapy Commercialization Symposium

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INTRODUCTION

The inaugural 2025 Cell Therapy Commercialization Symposium (CTCS), sponsored by McKesson and ADVI Health, and held in conjunction with the Association for Value Based Cancer Care (AVBCC) annual meeting, convened stakeholders from across the cell and gene therapy ecosystem to examine the barriers affecting the commercialization of cell and gene therapies (CGTs) in the United States. Over the course of the meeting, discussions focused on the realities of advancing CGT access into broader real-world care settings. Panelists – including, policymakers, government regulators, clinicians, manufacturers, and representatives of stakeholder groups such as the Foundation for the Accreditation of Cellular Therapy (FACT) - explored the evolving payment and reimbursement landscape, the need for regulatory review that is tailored to the complexity of CGTs, and the structural barriers that continue to limit patient access.

The following white paper presents a structured overview of those discussions to support future policy and commercial decision-making, including future clinical innovations and access opportunities. The sections that follow will 1) describe the specific barriers identified within each topic area, 2) outline emerging or proposed solutions discussed by the panelists, and 3) highlight cross-cutting themes relevant to CGT delivery across settings of care. Taken together, the discussions at CTCS reflected both the progress that is underway and the substantial work that remains to ensure that the promise of cell and gene therapy becomes a reality for all patients.

For the full conference agenda and the recorded panel discussions, please visit: https://avbcc.org/ctcs/

THE PATIENT JOURNEY

A patient's journey to accessing advanced therapies is often marked by significant and compounding challenges that reflect broader systemic gaps in the US healthcare and reimbursement landscape. Many patients must cross state lines to reach specialized centers because life-saving cell therapy treatments are not always available in their given state of residency, increasing the logistical and financial burden on families and caregivers. Even once a treatment path is identified, medical complications and insurance hurdles, such as securing multiple prior authorizations for both the therapy and associated treatments or procedures and drafting single case use agreements, can delay time-sensitive care. Patients frequently shoulder the responsibility of self-advocacy, navigating a fragmented system that may not present the full range of clinical trials or cell therapy options available. Telehealth and family caregiving can help bridge gaps post-treatment, but the cumulative experience reveals a journey characterized by delays, fragmentation, and inequitable access that disproportionately affects patients with life-threatening illnesses. Recent research from McKesson and CAR T Vision, and amplified by ARM, reveals that only 2 of 10 patients eligible for CAR T-cell therapy actually receive the treatment, leaving a noticeable gap in coverage for this vulnerable patient population.[1]

PROVIDER ACCESS CHALLENGES

Panelists described a healthcare system in which clinical innovation has outpaced the operational and financial capacity of CGT delivery, and time-worn reimbursement methodologies no longer align with current treatment paradigms. These gaps are especially evident in CAR-T delivery, which was initially developed and implemented in academic medical centers but has been slow to expand into community oncology due to overburdensome regulatory and payer requirements. By and large, this limited uptake in community settings is driven by several barriers, including payer coverage disparities, overly burdensome provider credentialing and accreditation requirements, provider and regulator education gaps, and site-of-care restrictions. Accreditation standards, while designed to ensure safety and product quality, often impose requirements beyond what community practices

can feasibly meet, or potentially should have to meet. In parallel, structural cost issues such as the absence of direct reimbursement for apheresis expose treatment sites to substantial risk. These financial pressures are especially cost prohibitive when combined with payer-driven authorization delays and variability in payment timing, concerns that were also echoed in the InspiroGene CGT Annual Report.2 Collectively, these challenges demonstrate how misalignment across the CGT value-chain continues to restrict expansion into broader and more accessible care settings.

For a copy of the InspiroGene CGT Annual Report, please visit: https://inspirogene.com/cgt-report/

INNOVATIVE PAYMENT MODELS

A central theme of CTCS was the recognition that outdated payment and reimbursement models are not adequately designed to support the complex delivery, small patient populations, and high-upfront costs associated with CGT. Outcomes-based payment models show promise but remain limited in adoption. CMS's Medicaid Cell and Gene Therapy Access Model represents incremental progress by enabling such contracting across most states, however, its scope is narrow and it is not fully configured to incorporate the diversity of CGTs entering the market.

Implementing outcomes-based arrangements in practice is challenging for several reasons: patients may change insurers during follow-up; long-term outcomes are difficult to track across fragmented systems; stakeholders may disagree on meaningful endpoints; and aligning provider-reported outcomes with claims data is complex. Taken together, these constraints limit the scalability of current models and highlight the need for more robust evidence to support long-term value assessments.

Ultimately, CTCS panelists emphasized that durability of response is a key factor in determining the value of CGTs. Because many products are initially approved based on relatively small, single-arm trials, the generation of high-quality real-world evidence will be critical in shaping future payment models and commercial success.

CHALLENGES IN MEDICARE AND MEDICAID COVERAGE AND PAYMENT

Policy and payment structures of Medicare and Medicaid present some of the most significant barriers to broader CGT access. Medicare sequestration continues to limit outpatient reimbursement while payment delays ranging from 180 to 280 days expose treatment institutions to prolonged financial pressure. Additionally, MS-DRG 018, while initially helpful, has gradually become a catch-all bucket for a wide variety of products, including CAR T cell therapy, other T cell immunotherapies and even gene therapies. This trend demonstrates the need for more granular grouping criteria for DRG design that can recognize the diversity of advanced therapies. Medicaid challenges are even more complex. Because each state sets its own coverage and reimbursement policies, patients face highly inconsistent access depending on their location. To navigate these challenges, treatment centers are exploring financial risk mitigation strategies, such as using specialty pharmacies, to help manage exposure to delayed or insufficient reimbursement. CTCS panelists also encouraged manufacturers to pursue early and ongoing engagement with CMS and to strengthen internal government-affairs expertise.

Overall, while CAR-T reimbursement has improved since its early days, panelists in this and across all sessions highlighted many ongoing payment and policy challenges as well as potential solutions, findings consistent with a recent white paper published by ADVI Health.3 For a copy of the white paper, please visit: www.advi.com

FDA FLEXIBILITY AND "FIT FOR PURPOSE"

Regulation of CGTs must balance flexibility with consistency to support innovation while ensuring predictability for sponsors. Flexibility should not imply lower standards but reflect that CGTs require pathways distinct from traditional drugs; however, excessive uncertainty can impede trial planning and early engagement with the FDA. Stakeholders favored terms like "fit-for-purpose" or "tailored approaches," emphasizing that once adapted standards are set, they must be applied uniformly. Tools such as platform technology designation and Advanced Manufacturing Technology (AMT) designation offer promising mechanisms to streamline review, particularly for companies pursuing multiple indications based on shared platforms. Because FDA decisions influence payer behavior, especially when the evidence is ambiguous or when products are approved in an accelerated pathway, regulatory clarity is essential to avoid restrictive coverage. Future opportunities include economic incentives, such as priority review vouchers tied to platform criteria, and a clear process for identifying technology features that could qualify for platform designation. Ultimately, coverage with evidence development is likely to become increasingly important, providing a practical way to balance limited early evidence with the need to ensure timely access for patients with serious or life-threatening conditions.

CONSIDERATIONS FOR COMMERCIAL PAYERS

While CAR T access remains constrained, panelists emphasized that key barriers extend far beyond formulary coverage, stemming instead from delayed or insufficient reimbursement, complex payer–provider–manufacturer dynamics, and the financial exposure faced by self-funded employers for high-cost therapies. Although CAR-T is typically covered under the medical benefit and outright denials are uncommon, speakers noted persistent tension between maintaining high-quality, specialized care and expanding access for patients who cannot travel long distances for treatment. Without decentralized care and treatment options beyond academic medical centers, panelists warned that access gaps will persist. Proposed solutions from the provider-payer panel included bundled episode payments that give providers flexibility to manage costs, as well as AI-driven authorization tools to reduce administrative friction. Stakeholders also highlighted the need for alternative accreditation pathways tailored to community treatment sites that enable greater participation and improved feasibility while maintaining appropriate quality standards. Overall, meaningful improvement in CAR-T access requires coordinated action across accreditation, benefit design, education, payment reform, and data infrastructure, rather than simply loosening payer restrictions.

IN CLOSING

The 2025 CTCS discussions highlighted both the significant progress and the formidable challenges that continue to shape the commercialization and delivery of cell and gene therapies. Across patients, providers, payers, and regulators, a shared theme emerged: advancing CGT access will require coordinated, cross-sector action that aligns clinical, operational, financial, and regulatory frameworks. While promising solutions are emerging, including tailored accreditation pathways, innovative payment models, and fit-for-purpose regulatory approaches, lasting progress depends on translating these insights into practical reforms. Ensuring that the promise of CGTs reaches all patients will require continued collaboration, investment, and policy modernization across the ecosystem.

It is our hope that conversations on these important issues will extend well beyond AVBCC's October Summit and continue through new regional meetings planned for 2026. To all who participated and attended, we appreciate your support and your contribution to the field, and to patients.

1.) CAR T Vision. CAR T Vision Report. Published June 2025. https://cartvision.com/

2.) InspiroGene by McKesson. 2025 Cell and Gene Therapy Report: Advancing the Future of Medicine. McKesson Corporation. Published October 9, 2025. https://inspirogene.com/cgt-report/

3.) ADVI Health. Delivering on CAR T-cell Therapy's Promise: Policy Solutions for the Next Era of Cancer Care. Published Nov 21 2025. https://www.advi.com/insight/delivering-on-car-t-cell-therapys-promise-policy-solutions-for-the-next-era-of-cancer-care/