White Paper

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Bridging the gap in cell and gene therapy: addressing operational and financial barriers to achieve sustainable access

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Cell and gene therapies (CGTs) represent a major transformation in modern medicine, offering the potential for cure in patients with serious and treatment-refractory diseases. However, despite this promise, real-world delivery remains highly constrained. This white paper synthesizes insights from a multidisciplinary advisory council of 21 healthcare professionals involved in CGT delivery, together with the authors' collective experience, to examine operational and financial barriers from a provider perspective and to identify strategies to support sustainable expansion of CGT programs across diverse care settings. While clinical management of CGTs has become increasingly standardized, operational and financial barriers continue to impede broader implementation. Product onboarding can often be a complex process, as treatment sites must navigate manufacturer-specific site qualification processes, quality standards, and compliance requirements that can result in significant administrative burden. At the same time, reimbursement processes remain complex and variable across payers, with high upfront costs and inconsistent coverage and reimbursement models that can contribute to institutional financial risk and treatment delays. Drawing on provider experiences and advisory council discussions, this white paper identifies opportunities to improve the sustainability and scalability of CGT delivery. Key priorities include greater standardization of manufacturer onboarding and contracting processes, improved reimbursement predictability, and enhanced alignment among manufacturers, providers, and payers. Addressing these challenges may help reduce administrative burden, mitigate financial risk, and support streamlined implementation of CGTs across both academic and community settings.

Plain language summary: Overcoming cost & logistics hurdles to improve access to cell & gene therapies

What is this article about? Cell and gene therapies (CGTs) are transformational treatments that could potentially cure patients with serious disease like cancer or rare genetic disorders. Despite US FDA approval and commercial availability of several CGTs, many patients still cannot access them easily. This white paper looks at real-world hurdles that stand in the way of offering these treatments at hospitals and clinics.

What were the results? The authors focus their analysis on two major roadblocks: operational complexity and financial risk. Treatment centers are met with a complex process in which each CGT manufacturer has their own specific legal contracts, training requirements and quality standards. Navigating all of the different and varying parameters and requirements can often delay treatment by 6–18 months or more. The high cost (into the millions of dollars), unpredictable insurance coverage and slow reimbursement of CGTs create massive financial risks for providers. Even after almost a decade since the first approval, CGTs are still mostly given at large or academic hospitals and require many patients to travel long distances to be treated.

Why is this important? Standardizing how CGT manufacturers work with treatment sites is necessary to increase accessibility to these treatments. Simpler contracts and predictable insurance payments can help lessen financial risk for more providers and could potentially allow more patients to get care closer to home.

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Shareable abstract: Cell and gene therapies offer curative potential, yet many patients still face barriers to accessing treatment close to home. Our new white paper delves into how streamlining contracting and payment models can bring these life-saving treatments to more treatment centers. #CGT #HealthcareDelivery #PatientAccess

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Keywords: CAR T-cell therapy • cell and gene therapy • financial risk • operational complexity • reimbursement • site onboarding

The field of cell and gene therapy (CGT) has evolved rapidly over the past decade, expanding from a limited number of investigational products to a growing portfolio of approved therapies across multiple disease areas [1–3]. As of March 2026, 48 CGTs have been approved by the US FDA, with more than 2000 additional products in development [1,4]. While this rapid growth highlights growing momentum in the CGT landscape, real-world implementation remains complex. The CGT value chain faces significant challenges as manufacturers, payers and treatment centers struggle to systematize critical aspects of treatment access and delivery.

Although numerous publications have examined barriers to CGT adoption, much of the existing literature has focused on patient access, reimbursement policy or broader health system considerations. Comparatively less attention has been devoted to understanding how providers and treatment centers experience the evolving operational and financial challenges associated with CGT delivery. This white paper integrates multidisciplinary and multi-institutional provider perspectives to examine how operational and financial challenges interact and influence treatment center readiness for commercial CGT delivery in the US. As the number of approved therapies grows, understanding and addressing provider-facing barriers will be critical to supporting expanded and more sustainable access to CGTs.

Understanding real-world delivery & readiness

Despite the growing number of approved CGTs, real-world delivery remains constrained within a highly centralized care model. Currently, the administration of CGTs is largely confined to a limited network of certified academic medical centers or authorized treatment centers [5]. Notably, access gaps persist across multiple CGT indications, highlighting the need to expand both the number and geographic reach of capable treatment centers to help reduce barriers related to travel distance, socioeconomic disparities and other logistical challenges [6–9].

At the same time, expanding access to CGTs is not straightforward. Barriers to broader adoption are multifactorial, spanning clinical, operational and financial frameworks. While evolving treatment guidelines and growing real-world clinical experience have improved the ability to administer CGTs, operational and financial challenges continue to impede widespread access [10–15]. Among the most significant obstacles to scalable delivery are challenges related to treatment-site activation and payer reimbursement [16,17]. When onboarding a CGT product, treatment centers often face resource-intensive site-qualification processes driven by manufacturer-specific requirements and fragmented contracting practices [5,17,18]. Reimbursement adds further complexity, as high upfront costs and variability in payer coverage policies can create uncertainty that can delay implementation and limit institutional willingness or ability to offer treatment [19–23].

To address these gaps, this white paper synthesizes insights from a multidisciplinary advisory council comprised of 21 experts involved in CGT delivery across diverse practice settings, including physicians, pharmacists, administrative health-system leaders and other stakeholders responsible for therapy implementation and administration. These perspectives are supplemented by the collective experience of the authors, many of whom are leaders in CGT delivery at their respective institutions and participated in the advisory council discussions. Convened between March 2025 and March 2026, the council identified recurring challenges related to CGT delivery and access, with two provider-facing barriers emerging as central themes: operational complexity as it relates to product onboarding and delivery, and financial challenges driven by reimbursement uncertainty and payer coverage processes. In the sections that follow, we examine the drivers of these barriers and explore opportunities to improve treatment center readiness and support sustainable CGT access.

Operational complexity in CGT onboarding & delivery

Contracting as a foundational driver of operational complexity

Expanding CGT delivery requires a coordinated system of complex clinical, operational and financial infrastructure that extends well beyond traditional treatment workflows [24]. Unlike conventional therapies, CGT delivery often necessitates a tightly integrated process encompassing patient identification, apheresis, manufacturing coordination, logistics, administration and post-treatment monitoring [25]. The design and execution of these clinical and logistical workflows are largely driven by manufacturer-provider contractual arrangements that govern how CGT products are accessed, managed and delivered [17].

Addressing CGT delivery barriers includes broader institutional awareness of the financial and operational implications of CGT manufacturer agreements. Contract negotiations shape not only legal risk, but also downstream workflows including product ordering, therapy administration, data exchange and financial risk. Each manufacturer often requires its own set of product-specific agreements, ordering systems, handling protocols, audit expectations and compliance processes [26,27]. While these requirements can create administrative burden, they are often driven by the need to meet product-specific safety, quality and regulatory standards. For example, to ensure product integrity and patient safety, many CGTs require rigorous chain-of-identity and chain-of-custody processes, including documented tracking, patient-product verification and validated procedures for product shipment, receipt, storage and preparation [28–30]. Accordingly, a certain degree of product-specific qualification and onboarding is necessary to support safe and compliant delivery.

However, onboarding a new CGT product can also be a lengthy and resource-intensive process as treatment centers must devote significant time to contract review, workflow development, staff training and other manufacturer qualification activities. Published reports have demonstrated that completing these requirements may take 6–18 months or more before a treatment center is authorized by the manufacturer to deliver a given CGT [17,18,31,32]. Advisory council experts consistently identified manufacturer-specific contracting requirements as a major contributor to implementation burden, particularly for smaller and under-resourced treatment centers seeking to offer multiple CGT products. Although many of the underlying requirements are often similar, treatment centers must repeatedly navigate different processes and documentation standards for each product, creating substantial administrative burden that can discourage onboarding of multiple therapies.

Treatment center activation for CGT often requires negotiation and execution of multiple agreement types, including a master services agreement (MSA), quality agreement, and product trade agreement, each governing different aspects of the manufacturer–treatment center relationship [17] MSAs are intended to serve as the overarching framework governing the commercial relationship between manufacturers and treatment sites, while trade and quality agreements describe responsibilities related to product handling, administration, monitoring and oversight throughout treatment [17]. During the advisory council discussions, provider experts reported substantial variation in the structure, scope and terminology for these agreements across manufacturers. Frequently described challenges included redundant provisions, lack of standardization across different agreement types (e.g., MSAs, trade and quality agreements), unclear role responsibilities, inconsistent trade and title terms and overly complex legal language that introduces ambiguity for treatment center personnel. Collectively, provider experts described these contracting-related challenges as among the most burdensome aspects of the treatment center onboarding process, with implications for both treatment center readiness and long-term sustainability of CGT program delivery.

Financial risk & reimbursement complexity in CGT delivery

Reimbursement complexity and financial risk remain among the most significant constraints to broader adoption. CGTs often involve high upfront cost density, complex reimbursement workflows and fragmented payer review processes that can create substantial financial risk if not properly managed [18,19,24]. In practice, coverage criteria and prior authorization (PA) review standards vary significantly across payers, and review timelines can often extend 30 days or longer, particularly when appeals processes are necessary [18]. Additionally, payers often differ in the scope and specificity of required clinical documentation [33]. Advisory council experts noted that incomplete documentation or gaps in supporting evidence frequently interrupt the review process, prolonging authorization timelines and delaying treatment initiation. Similarly, reimbursement operations require a high degree of precision, as coding errors, billing inaccuracies or discrepancies between authorized services and submitted claims can result in payment denials or delays [34]. Real-world reimbursement assessments in chimeric antigen receptor (CAR) T-cell therapy have highlighted the extent of the challenges that can arise with complex CGTs. In a 2026 institutional analysis of 45 treated patients, more than half of submitted claims (57%) experienced at least one reimbursement-

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related issue, contributing to payment timelines exceeding 4 months and unresolved claims resulting in millions of dollars in outstanding reimbursement exposure [21].

It is worth noting that, historically, many commercial payers have often adapted existing transplant-based reimbursement models for CGTs because their delivery draws on many of the same specialized teams, inpatient resources and institutional capabilities required for hematopoietic cell transplantation [35,36]. While transplant frameworks may offer a familiar point of reference for payers, experts on the advisory council noted that CGT care pathways often include clinical and operational requirements that do not align fully with traditional transplant workflows, creating important implications for coverage and provider network participation. In many cases, contracting is managed through narrow transplant center of excellence networks, which can create barriers to payer network inclusion, particularly for community-based providers [37,38]. Published reports indicate even capable community sites that are accredited by the Foundation for the Accreditation of Cellular Therapy and experienced in CGT clinical care continue to face barriers in securing broad payer network inclusion, often forcing patients to travel long distances to access in-network facilities and incur substantial time and financial burden [35,39].

Case-rate models, single-case agreements & administrative burden

Case-rate reimbursement reflects another challenge associated with applying transplant-based payment models to CGT delivery. Although commonly used for autologous cell therapies such as CAR T-cell therapy, case-rate structures are not standardized across commercial payers [40,41]. As a result, provider experts cautioned that treatment centers often face inconsistency and variability regarding when an episode of care begins, which services are included in the bundled payment, and for how long that coverage extends. This variability across payers can complicate cost-to-serve calculations and financial forecasting, particularly for sites with limited CGT experience.

Additionally, CGT coverage is often managed through single-case agreements (SCAs), which can be lengthy and complex [18,40]. Negotiating SCAs for each patient introduces additional administrative burden and can delay time to treatment for up to several weeks, even when clinical eligibility is clear [18,42]. Real-world studies have shown that SCA requirements are associated with longer treatment timelines, with time-to-treatment measures reported to be up to twice as long for patients requiring an SCA compared with those who do not [42–44]. In the setting of serious, rapidly progressing disease, delays can have devastating clinical consequences for patients [42]. For treatment centers without dedicated financial resources or contracting specialists, experts on the advisory council noted that this process can become a substantial limiting factor, increasing both operational workload and financial exposure.

Cost-to-serve complexity & financial exposure

Beyond reimbursement for the CGT product itself, advisory council experts emphasized that treatment centers often must absorb a range of variable and often underappreciated service costs, including apheresis, cryostorage, facility and infrastructure development, reporting and compliance and management of treatment-related toxicities. The ability to recover the total cost-to-serve is heavily influenced by payer mix, as reimbursement adequacy and timing differ substantially across commercial plans, Medicare and Medicaid [45,46]. When these factors are not fully captured within reimbursement models, treatment centers may underestimate the true cost of CGT delivery, resulting in unanticipated financial exposure. While treatment centers may not typically set out to intentionally restrict patient volume, sustained reimbursement uncertainty and cash flow risk can ultimately lead sites to limit the number of patients they are able to treat with CGT, thereby constraining access despite clinical demand [47].

Opportunities to support more efficient & sustainable CGT delivery

Although no single solution is likely to address all barriers to CGT delivery, greater alignment across manufacturers, payers and treatment centers may help address several of the operational and financial complexities that currently limit patient access. Drawing on the perspectives of the advisory council experts, the following considerations are intended to highlight potential strategies that may help reduce operational burden, improve reimbursement alignment and support the long-term sustainability of CGT programs, with key recommendations summarized in Table 1.

Table 1. Major provider-facing barriers and cross-stakeholder recommendations to support sustainable cell and gene therapy delivery.

Major barrier	Key recommendations
Manufacturer-specific site qualification and onboarding requirements	Standardize common onboarding and maintenance requirements across manufacturers while retaining product-specific safety and quality elements. Leverage existing accreditation and treatment-center quality infrastructure where appropriate.
Fragmented contracting across master services, trade and quality agreements	Increase consistency in terminology and core provisions, including roles, responsibilities, accountability, trade and title terms, and management of deviations or disruptions. Separate commercial contracting from clinical research activities and incorporate multidisciplinary review early in the process.
Duplicative audits, training, reporting, portals and operational workflows	Reduce redundant audits and documentation, establish reasonable review frequencies, streamline education and reporting requirements and promote more consistent technology platforms.
Variable payer coverage, PA, network participation and documentation requirements	Improve transparency and consistency in payer coverage and network participation criteria. Establish designated CGT payer contacts who understand payer-specific authorization and documentation requirements.
Inconsistent case-rate definitions and reimbursement structures	Clearly define the episode duration, services included, reimbursement of the CGT product, exclusions or carve-outs and factors that may create financial exposure. Consider broader global case-rate arrangements as experience increases.
Incomplete recognition of total cost-to-serve and reimbursement risk	Account for the full range of product-related and clinical service costs, assess the effects of payer mix and variable resource utilization, and establish processes to monitor claims, payment and outstanding financial exposure.
Fragmented coordination across payer and treatment-center functions	Establish dedicated points of contact to coordinate authorization, contracting, clinical documentation, billing, and payment throughout the CGT treatment journey.

CGT: Cell and gene therapy; PA: Prior authorization.

Reducing complexity in product onboarding

A key recurring theme across advisory council discussions was the opportunity for greater standardization across manufacturers, particularly in quality agreements, to reduce redundancy and accelerate onboarding. Although complete uniformity may not be feasible, greater consistency across manufacturers with respect to roles and responsibilities, accountability and the management of deviations and disruptions could help align expectations among manufacturers, treatment centers and third-party vendors.

Beyond standardization of quality agreements, experts emphasized the importance of reducing unnecessary complexity within broader contracting and onboarding processes. Setting reasonable guidelines for frequency of standard operating procedure audits and reviews can help prevent unnecessary administrative burden while maintaining compliance and quality. Separating contracting pathways for commercial CGT delivery from those used in research or clinical trials can further reduce complexity and avoid misalignment. For manufacturers operating with European or global access strategies, agreements should explicitly reflect US FDA regulatory requirements and clarify that EU or non-US regulatory frameworks do not apply to US-based treatment sites. Experts also cautioned against incorporating mutable website links and references to external policies and documents within agreements, noting that these may introduce unnegotiated changes and create unintended risk for clinicians, institutions, and patients.

From the provider perspective, effective contract review increasingly requires multidisciplinary input [24]. Experts cautioned that legal review alone may be insufficient; incorporating clinical, operational, pharmacy, and financial expertise helps ensure that contractual terms are aligned with real-world workflows and patient care needs. Embedding these perspectives early in the contracting process can mitigate downstream disruptions and support more predictable and sustainable CGT delivery.

Importantly, key stakeholder organizations are working to reduce unnecessary variation and duplication in CGT implementation. The American Society for Transplantation and Cellular Therapy (ASTCT) 80/20 Task Force estimates that approximately 80% of clinical site onboarding and maintenance processes exhibit similarities across different manufacturers of commercial immune effector cell therapies [5]. The task force proposed reducing duplication in site accreditation and auditing, streamlining education and reporting requirements, standardizing supporting technology platforms and using common terminology, while preserving product-specific requirements and critical quality attributes where necessary. Similar efforts to simplify overlapping requirements have also occurred at the regulatory level. In June 2025, the FDA eliminated separate Risk Evaluation and Mitigation Strategy (REMS) requirements for all autologous CAR T-cell therapies, including product-specific treatment-

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site certification requirements [48–50]. This example illustrates how common requirements can be consolidated or removed, especially as experience and supporting evidence mature, helping to reduce institutional and logistical burden associated with CGT delivery [50].

Toward more sustainable reimbursement alignment

Although greater standardization and streamlined onboarding processes may help reduce operational burden, advisory council participants emphasized that long-term viability of CGT programs will also depend on reimbursement models that align with the clinical, operational and financial realities of CGT delivery. As treatment centers assume responsibility for increasingly complex care pathways, reimbursement arrangements must provide sufficient clarity and predictability to support sustainable program operations. In this context, experts highlighted the importance of clearly defining case-rate arrangements, including the duration of the episode and services covered, to reduce ambiguity and facilitate financial planning. Establishing this level of clarity may also create opportunities for more standardized reimbursement arrangements over time. As payer and provider experience with CGTs matures, global case-rate agreements may offer a more efficient alternative to repeated patient-specific contracting [36]. For these arrangements to be sustainable, however, treatment centers must maintain a clear understanding of reimbursement terms, including what is covered, how product costs will be reimbursed, and where financial exposure remains, including changes in product cost, variation in resource utilization and treatment-related complications [40].

Clear reimbursement terms alone, however, may not be sufficient to ensure predictable payment. Advisory council participants emphasized that the way payers and treatment centers coordinate throughout the process can substantially affect the administrative burden of CGT delivery. Providers described dedicated payer case managers as particularly helpful when available, serving as consistent points of contact for coordinating PA requests, clarifying coverage requirements and addressing potential gaps before treatment. Within treatment centers, advisors highlighted the importance of dedicated personnel with detailed knowledge of payer-specific policies and reimbursement pathways to support PA submissions, confirm required clinical documentation, coordinating SCAs, and monitoring claims through payment. Consistent with these recommendations, published treatment center experience describes similar models of dedicated CGT personnel and multidisciplinary teams coordinating payer requirements, PA and financial oversight to support the efficient management of CGT delivery [24,51].

Limitations

The findings and recommendations presented in this paper should be interpreted in the context of several important limitations. First, this white paper is informed primarily by discussions with a multidisciplinary US provider advisory council and supplemented by a targeted narrative review rather than a systematic assessment of the evidence. The barriers examined were not formally ranked, and the literature was not graded to compare the relative strength or importance of evidence across the different findings and recommendations. Moreover, the perspectives shared may not reflect all treatment centers or stakeholder groups, and the focus on FDA approved therapies as well as US delivery and reimbursement models may limit generalizability to other healthcare systems. Additionally, much of the available evidence and experience relates to CAR T-cell therapy, with less published data for other CGT modalities. Nevertheless, many CGTs share similar operational and reimbursement complexities, making the challenges and observations discussed in this paper relevant beyond CAR T-cell therapy. Finally, several proposed solutions are provider-informed and operationally plausible but have not been formally shown to reduce delays, improve access or lessen institutional burden.

Conclusion

As CGTs become increasingly integrated into routine clinical practice, successful adoption will depend on whether the operational and financial systems supporting delivery can evolve alongside clinical and scientific progress. The advisory council identified opportunities to reduce complexity through standardization of manufacturer onboarding and contracting requirements, clearer and more predictable case-rate and reimbursement structures, and stronger coordination between payers and treatment centers throughout authorization, contracting and payment. Future work should evaluate how these strategies can support expansion beyond established academic centers into more community and geographically dispersed care settings, helping to sustain treatment-center readiness and improve patient access.

Summary points

- Cell and gene therapies (CGTs) are transforming modern medicine, offering curative potential for refractory cancers, rare diseases and genetic disorders.
- Treatment-center readiness remains a critical constraint to CGT access, with operational and financial barriers limiting broader adoption beyond established centers.
- Manufacturer-specific contracting, onboarding and site qualification requirements create substantial administrative burden and can delay treatment-center activation by months.
- Although many onboarding requirements are similar across products, variation in agreements, processes and documentation standards often requires treatment centers to duplicate efforts across multiple CGTs.
- Reimbursement complexity, prior authorization requirements and payer-specific coverage policies create uncertainty that can delay treatment and increase financial risk for providers.
- Single-case agreements and non-standardized case-rate arrangements add administrative burden, complicate financial forecasting and may prolong time to treatment.
- Greater alignment across manufacturers, payers and treatment centers, including standardized onboarding practices, clearer reimbursement frameworks and stronger payer-provider coordination, may support more sustainable CGT delivery and improve patient access.

Author contributions

All authors (GL Simmons, RE Richards, IM Borrello, M Mortel, J DePinto, EC Pittos) were responsible for white paper conception, drafting and revision of the manuscript. EC Pittos was responsible for final approval.

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