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Cell & Gene Therapy Expansion:

The Evolution of CGT Delivery in the U.S.

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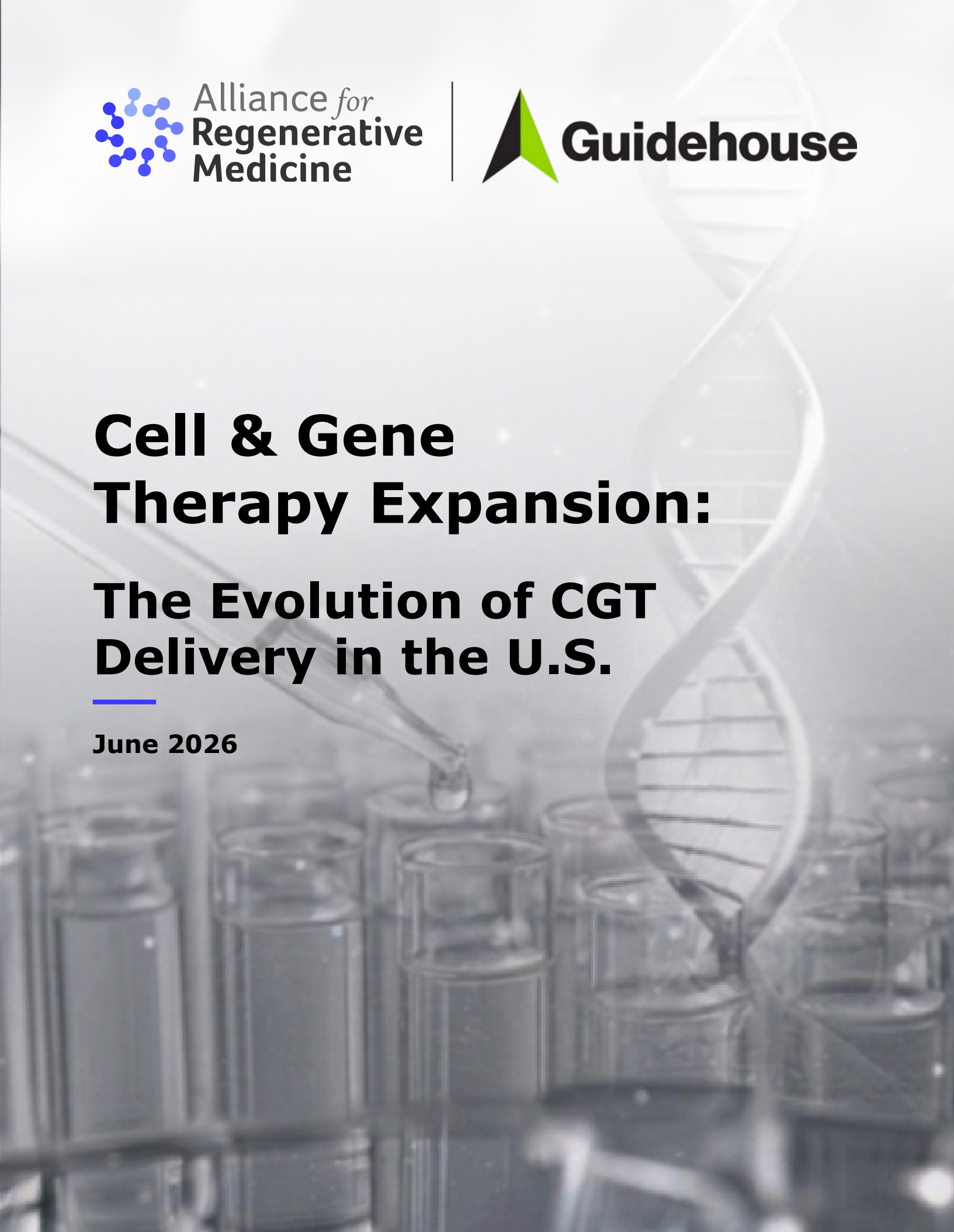


1 SUMMARY

Cell and gene therapy (CGT) products are complex biologic medicines that often require specialized, more resource-intensive patient care, close monitoring, and longitudinal follow-up. As such, early CGT delivery in the United States (U.S.) was highly centralized in academic centers, reflecting the need for dedicated infrastructure, clinical expertise, and tight operational control. This model limited patient access by creating additional burdens for patients and providers. However, CGT delivery is evolving as market experience grows, clinical evidence matures, regulators ease certain requirements, and the treatment network expands beyond early academic hubs.[1] This whitepaper leverages U.S. claims data on select CGT products to examine the evolution of CGT delivery beyond the early academic-focused model. The CGT products for which the claims data were reviewed and analyzed in this work are those that were FDA approved between 2017 and 2025 with significant claims volume (ABECMA™, BREYANZI™, CARVYKTI™, CASGEVY™, ELEVIDYS™, HEMGENIX™, KYMRIAH™, LUXTURNA™, LYFGENIA™, ROCTAVIAN™, TECARTUS™, VYJUVEK™, YESCARTA™, ZEVASKYN™, AND ZOLGENSMA™).

The analysis shows a 740% increase in the volume of CGT administration-related claims from 2018 to 2025, with new administering sites also appearing beyond major metropolitan areas.[2] For example, community centers now represent more than 45% of the CGT treatment network.[2] This expansion has improved patient access, with out-of-state travel for CGT treatment falling to ~18% of total CGT claims in 2025, down from ~30% in 2018, signaling that care is moving closer to home and the delivery network is becoming less restrictive.[2] At the same time, the expansion of CGTs into earlier lines of treatment and the emergence of treatments for more prevalent diseases will strain existing capacity. For developers, this marks a strategic inflection point: how to achieve delivery across a more decentralized treatment landscape. In that regard, success will depend on proactively designing a fit-for-purpose CGT delivery network, pressure-testing access and affordability requirements early, building integrated evidence and value plans, and establishing site readiness and enablement capabilities needed to deliver CGTs consistently at scale.

2 CGT DELIVERY WAS INITIALLY CENTRALIZED BY NECESSITY

In the first wave of U.S. CGT launches, delivery was centralized in academic centers due to a need for highly specialized teams and hospital infrastructure **(Figure 1)**.[2] The high concentration of CGT claims (>67%) in a handful of select states including Florida, California, Ohio, Illinois, and Maryland reflected this academic center-first approach, as patients traveled across state lines to receive treatment at established administering sites.[3] Driven by uncertainty around side-effect management, operational reliability, and regulatory and payer expectations, this early centralization prioritized safety and consistency over breadth of access. While effective at mitigating risk, this model was not built for broad CGT adoption, and launch strategies remained centered on a smaller number of highly specialized, well-equipped centers.

Figure 1: Distribution of CGT treatment volume by state and site-of-care (2018)[2]

State Ranking by CGT Treatment Volume

Proportion of Academic vs. Community Claims

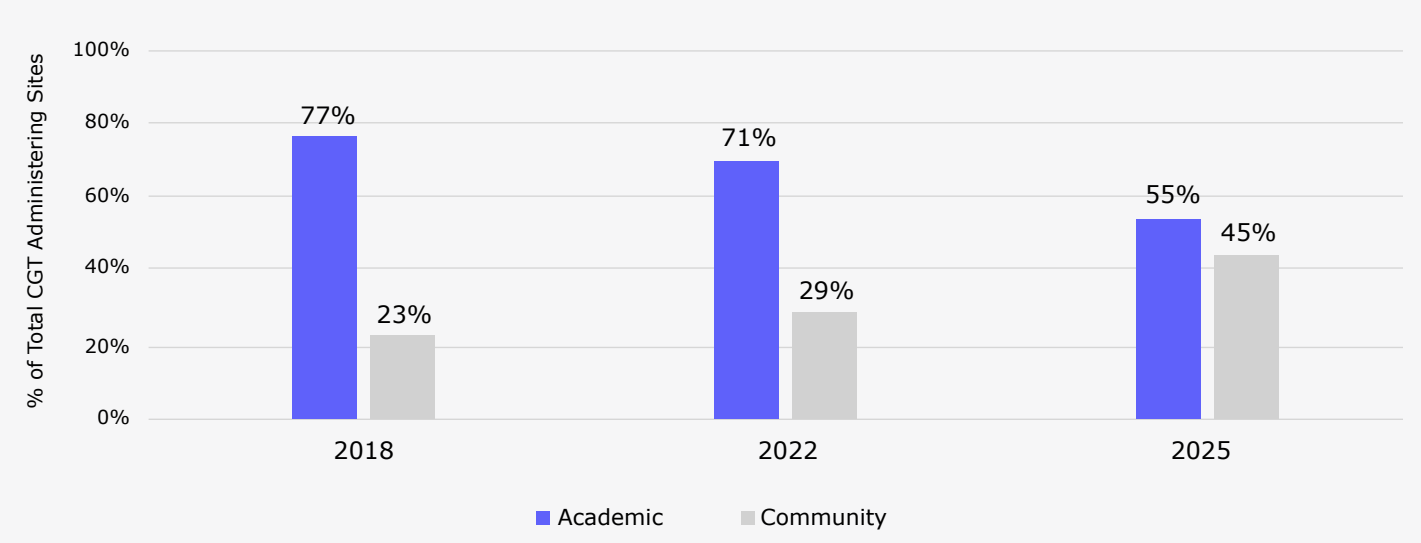
Ranking, 2018	**% U.S. Total**	**Academic**	**Community**
1. Florida	32.5%	98%	2%
2. California	11.8%	100%	0%
3. Ohio	11.0%	100%	0%
4. Illinois	6.1%	100%	0%
5. Maryland	6.0%	100%	0%
Total	**67.4%**	**99.6%**	**0.4%**

Over time, clinical management has become more standardized, training more repeatable, and accreditation more accommodating of qualified community settings, enabling the CGT delivery network to expand beyond the first wave of academic-center-led launches.

3 SHIFTING REQUIREMENTS HAVE ENABLED NETWORK EXPANSION

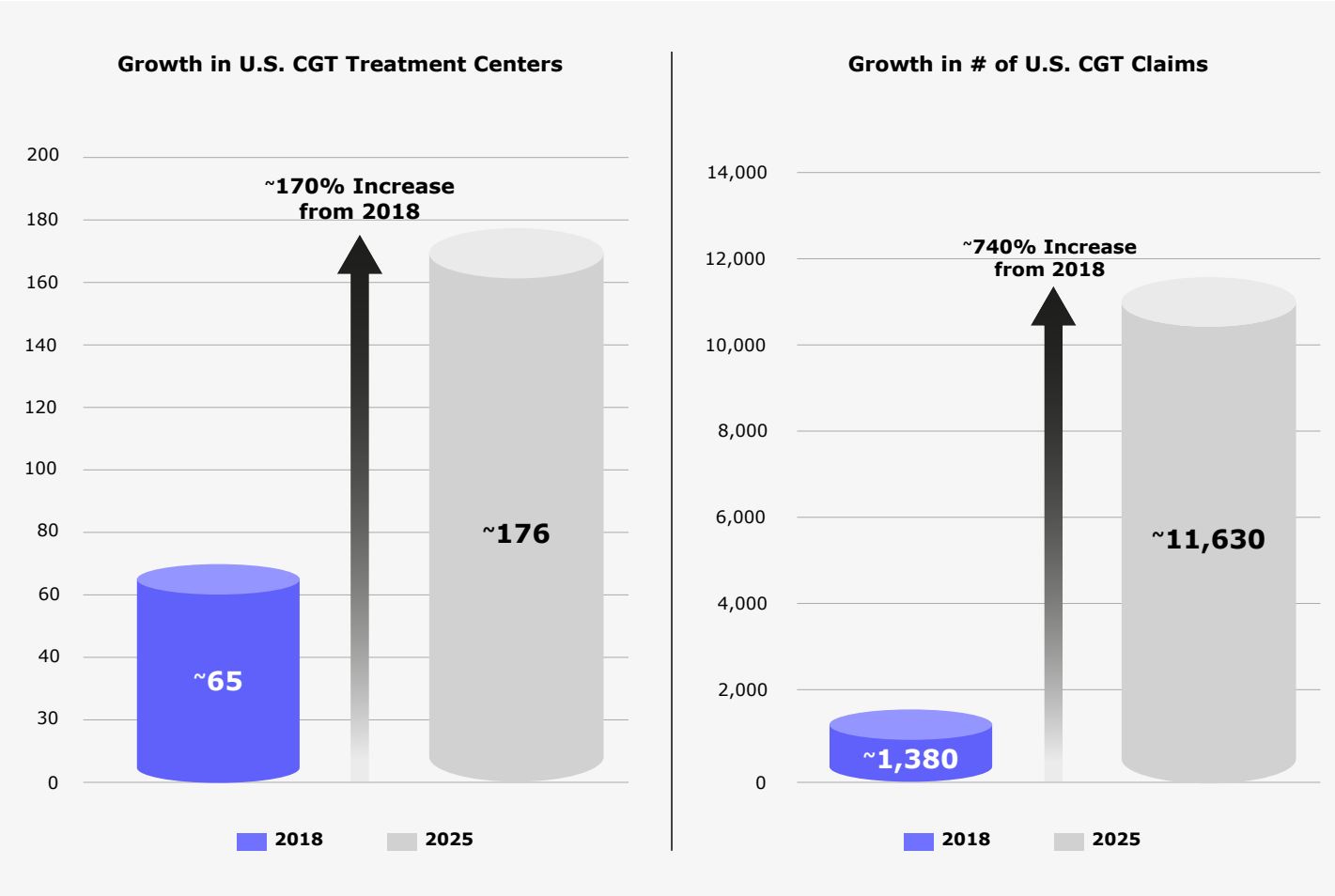
The CGT delivery network has scaled since the first wave of approved CGT products, such as LUXTURNA, YESCARTA, and KYMRIAH, with more centers building the capacity to administer treatment. In 2025, community centers accounted for 45% of the total sites administering CGTs, up from 23% in 2018 **(Figure 2)**.[2] What began in a small set of academic centers has evolved into a broader mix of large treatment sites and community providers. This shift does not replace academic centers; rather it reflects a more distributed model in which capable community providers complement academic hubs. This trend is expected to accelerate due to the U.S. Food and Drug Administration's June 2025 removal of Risk Evaluation & Mitigation Strategy (REMS) requirements and the addition of more patient-friendly label updates for CD-19 and BCMA-directed autologous CAR-T therapies.[1]

Figure 2: Relative distribution of academic & community CGT administering sites (2018 vs. 2022 vs. 2025)[2]



Geographically, CGT delivery is expanding within and beyond major cities. In 2018, 100% of the ~65 CGT administering sites captured in claims data were in urban, metropolitan areas, as these settings are more likely to have the highly specialized infrastructure and capabilities required to deliver CGTs.[2] By 2025, delivery in ~176 centers captured in claims data remained primarily urban-based, although four new centers emerged in non urban areas. Over this period, the number of CGT administering sites increased substantially (+170% from 2018 to 2025), and the number of CGT claims grew approximately seven-fold.

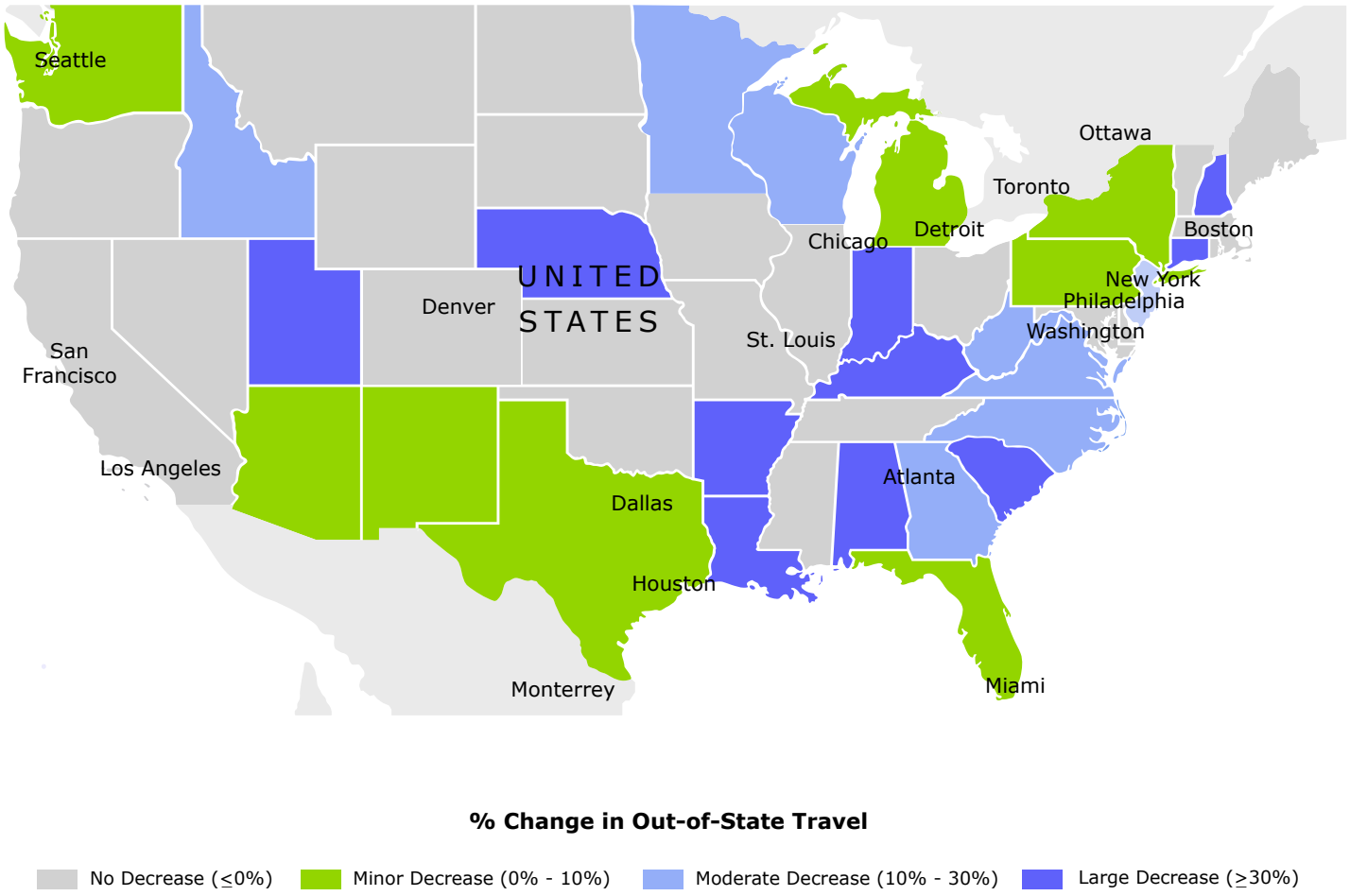
Figure 3: Growth in U.S. CGT claims and treatment centers (2018 vs. 2025)[2]



Expansion is also showing up in capacity, not just center count. The number of high volume centers administering more than 100 CGTs per year grew significantly, from one center in 2018 to 21 centers in 2025,[2] indicating deeper capability across the network and less dependence on a handful of early centers.

In parallel, access is improving, as the overall share of CGT patients traveling out of state declined from ~30% to ~18% from 2018 to 2025, with decreases seen across 26 states.[2] This suggests that network expansion is translating into treatment closer to home for more patients **(Figure 4)**. This has important access implications, as receiving care more locally can mitigate non-clinical barriers such as time off work and travel logistics, which may increase the overall number of patients treated with CGTs and reduce time-to-treatment.[4]

Figure 4: Decrease in proportion of patients treated with CGTs seeking treatment out of state (2018 vs. 2025)[2]

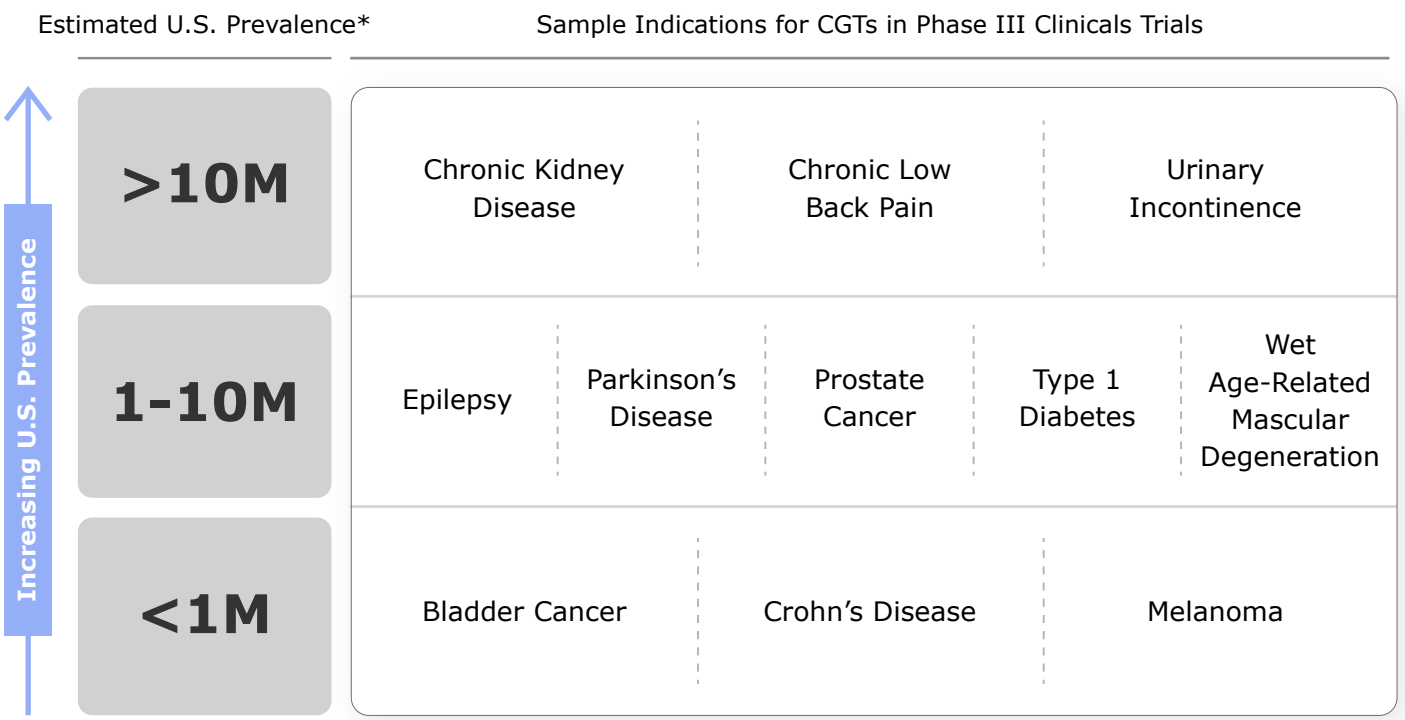


At the same time, a broader treatment network increases the risk of variability.[5] Differences in experience, staffing, training, and escalation processes can create uneven execution. These inconsistencies can drive more escalations, reduce center satisfaction, and increase payer scrutiny, especially as payers evaluate site of care, total cost, and outcome reliability across settings. The implication for CGT developers is that future access strategies should be built for a mixed ecosystem, with the right infrastructure, standards, and support to enable seamless expansion into the community setting.

4 THE NEXT WAVE CREATES NEW OPPORTUNITIES FOR SCALE

The next challenge is not whether networks can expand but whether they can absorb a materially higher volume as CGTs move into earlier lines of therapy and more prevalent conditions. While most programs still focus on oncology and rare genetic diseases, late-stage development is emerging in high-volume disease areas, including chronic kidney disease, epilepsy, Parkinson's disease, and Type 1 diabetes.[6,7] While these conditions may represent a smaller relative share of the pipeline, they have the potential to create a significant increase in future CGT volumes **(Figure 5)**.[6,7]

Figure 5: Late-stage CGT pipeline (Phase III) is expanding into higher prevalence indications[6,7]



*Prevalence figures reflect total disease population; CGT eligible patients may represent a subset of the total disease population (GlobalData, May 2026).

These programs differ from first-wave launches because they target larger, more varied patient populations and have the potential to generate volumes significantly exceeding that of current CGTs. As a result, the ability to deliver therapy may become a main limiting factor for launch performance. Without proactive network design, manufacturers risk slower uptake, payer-driven restrictions on where therapy can be given, and "success stalls" where demand outpaces operational capacity.

5 WHAT SHOULD BE DONE NOW TO PREPARE

Recent developments have further accelerated the shift toward broader CGT access. For example, the removal of REMS requirements and label updates for CD19- and BCMA-directed autologous CAR-T therapies, including reduced proximity requirements to administering sites and post-treatment driving restrictions, suggests that a wider set of centers may now be able to participate in CGT delivery.[1,8]

As CGT delivery evolves from a centralized, academic-led model to a broader, more distributed network, the primary challenge is continuing to scale delivery. To prepare, developers should consider four key actions to ensure that growing demand can be met without operational bottlenecks:

Develop a fit-for-purpose CGT care delivery strategy that addresses health system readiness, site economics, operational capacity, referral pathways, and patient access across academic and community settings

Pressure-test access, reimbursement, and affordability requirements early with payers, providers, and other stakeholders to reduce downstream barriers to adoption

Create an integrated evidence and value plan that supports coverage, site-of-care flexibility, patient burden reduction, and standardized delivery across settings

Build a launch readiness and site enablement model that includes site qualification, training, operating protocols, escalation pathways, patient support, and ongoing performance management

A fit-for-purpose network strategy will enable faster uptake at launch, improve geographic reach, and reduce the need for patients to travel long distances for care. Standardization efforts will also support more consistent outcomes across sites and mitigate payer concerns around variability, while earlier integration of access planning will strengthen value narratives and support broader coverage. Together, these efforts position organizations to avoid capacity-driven slowdowns and sustain adoption as CGTs scale.

6 GLOSSARY AND SOURCES

Abbreviations:

- CAR-T – Chimeric Antigen Receptor T-cell
- CGT – Cell & Gene Therapy
- REMS – Risk Evaluation & Mitigation Strategy

Additional Details and Definitions:

- **Academic Medical Centers** – Centers formally affiliated with one or more accredited medical schools or that have active residency or fellowship programs
- **Community Centers** – Independent hospitals or clinics primarily focused on direct patient care, without formal medical school governance or responsibility for accredited residency or fellowship programs (i.e., also do not have Academic Medical Center Designation)
- **Metropolitan Centers** – Centers with ZIP codes matched to RUCA (Rural Urban Community Area) and equal to 1
- **Urban Centers (incl. Metropolitan)** – Centers with ZIP codes matched to RUCA (Rural Urban Community Area) and less than 3
- **Non-Urban Centers** – Centers with ZIP codes matched to RUCA (Rural Urban Community Area) and more than 3
- ***Cell & gene (CGT) therapies*** – ABECMA, BREYANZI, CARVYKTI, CASGEVY, ELEVIDYS, HEMGENIX, KYMRIAH, LUXTURNA, LYFGENIA, ROCTAVIAN, TECARTUS, VYJUVEK, YESCARTA, ZEVASKYN, AND ZOLGENSMA

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