

2025 Cell and Gene Therapy Report:

Advancing the Future of Medicine

CGT pipeline signals a new era of therapeutic innovation

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Providers see promise in CGT but face persistent barriers to care

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Payers weigh value as they shape CGT coverage decisions

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Location continues to shape patient access to CGTs

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InspiroGene™
By McKesson



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“

The CGT field is reaching an inflection point. Progress is undeniable, but so are the structural barriers standing in the way of broader access and sustainable delivery.

”

— Joe DePinto
Head of Cell, Gene, and Advanced Therapies,
McKesson

Turning momentum into movement: Cell and gene therapy at a turning point

Behind every advance in cell and gene therapy (CGT) is a patient waiting for something more—more time, more hope, more options. These are not abstract innovations; they’re breakthroughs with the power to change lives.

When we launched our inaugural CGT report last year, we were humbled by the response it received. It sparked important conversations across the healthcare ecosystem about how we can collectively unlock the full potential of these transformative therapies. We’re eager to continue that dialogue with the 2025 Cell and Gene Therapy Report. This year, we set out not only to reflect on how the field has progressed, but to dig deeper into what it will take to bridge the gap between innovation and access.

The past 12 months have been marked by both remarkable scientific progress and a growing awareness of the challenges still holding CGTs back from broader adoption. The science is advancing at a pace that was unthinkable just a few years ago. Promising solid tumor therapies are progressing through clinical trials. Dual-target CAR T therapies are demonstrating objective response rates of 80-100%, and we’re seeing CGTs move into earlier lines of treatment.¹ Meanwhile, new pipeline data are beginning to show efficacy in disease areas previously untouched by this class of therapies, such as diabetes and lupus, which could dramatically expand the CGT footprint in years to

come. As the therapeutic reach of CGT continues to expand, so too does the urgency to solve for scale.

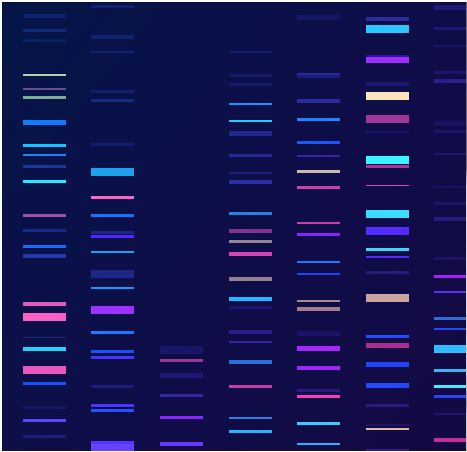
We’ve also seen important regulatory changes that may drive broader access in the future. The FDA’s decision to remove the Risk Evaluation and Mitigation Strategy (REMS) requirement for some CGTs—and to reduce the recommended patient stay near treatment centers from four weeks to two—has the potential to make it easier for patients and their families to travel to receive treatment.² And a new process proposed by the FDA’s drug and biologics centers under Rare Disease Evidence Principles (RDEP) to approve gene therapies for ultra-rare diseases based on one single-arm study could make certain treatments available to patients sooner.³



At the state level, Texas recently passed legislation removing certain FACT accreditation requirements,⁴ a shift that aims to enable more treatment centers to administer CGTs, particularly in rural areas.

Continued on following page

Other states are considering similar legislation, which could further decentralize care delivery. These changes represent a shift in how governing bodies view the delivery of CGTs: less as an experiment and more as a viable, scalable treatment option.



These are encouraging signs that our system is beginning to adapt to the realities of CGT. But as with any paradigm-shifting innovation, progress is not without complexity. CGTs continue to face many headwinds, particularly related to regulatory approvals and commercial uptake.

Recent leadership and staffing changes within the FDA's CGT review teams have created some uncertainty about the future of approvals. Agency officials had projected 10-20 CGT approvals annually by 2025,⁵⁻⁷ yet approvals to date this year have been behind the pace.⁵⁻⁶ Whether this trend is temporary or indicative of a longer-term slowdown, it has added a layer of unpredictability for companies working to bring therapies to market. While the FDA's prioritization of curative treatments is encouraging, there is still uncertainty about the implications of recent changes on development and commercialization timelines.

Operational challenges also persist, especially in the effort to expand CGT

into community care settings. Many health systems outside of academic centers are not yet equipped with the necessary infrastructure, staffing, or reimbursement models to deliver these therapies. That creates a system in which access is limited not by science, but by geography and resources.



The result is a growing disparity between where CGTs can be delivered and where patients live: a gap that threatens to undermine the promise of these therapies for too many communities.

Reimbursement also remains one of the top-cited and most critical barriers to access. Without sustainable

reimbursement strategies, commercial viability remains elusive, and patients will continue to face coverage delays or denials that may have life-altering consequences. New payment models are emerging as potential solutions, but they have not been consistently adopted or applied. A unified, cross-stakeholder approach is needed to ensure that reimbursement keeps pace with the science.

The CGT field is reaching an inflection point. Progress is undeniable, but so are the structural barriers standing in the way of broader access and sustainable delivery. That brings us to a critical question: How do we exponentially drive broader patient access and more commercial uptake of CGTs today and in the future? Because if we can't figure out how to commercialize these therapies at scale, the promise to patients will never be realized.

To help answer this question, we've designed this year's report around a rich set of insights drawn from across the ecosystem. We've collected a robust set of research and expert perspectives from stakeholders across the industry, including providers, payers, and other experts. The insights



that emerged showed a complex but navigable path forward that requires collaboration, innovation, and bold thinking from every stakeholder in this space.

Our team remains deeply optimistic about that path. InspiroGene™ by McKesson is proud to support CGTs from clinical development through commercialization. We help biopharma partners bring therapies to market efficiently, provide sites of care with the tools and support they need to

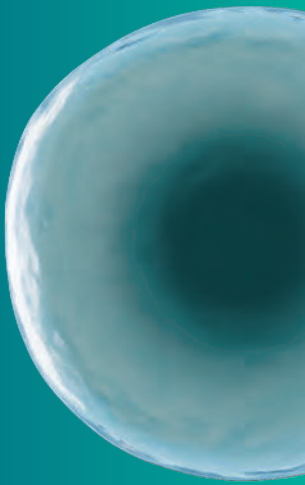
deliver CGTs safely, and work across the reimbursement landscape to help remove barriers to access.

In every conversation we have with manufacturers, providers, payers, and policymakers, we're reminded of the extraordinary shared commitment across this industry to ensure that no patient is left behind. We see firsthand the ingenuity, determination, and compassion that fuel this space, and we are committed to doing our part to turn that energy into real-world impact.

The journey ahead won't be easy, but it's one worth taking, and one we are proud to walk alongside our partners. ●

Joe DePinto
Head of Cell, Gene, and Advanced Therapies, McKesson

“Behind every advance in cell and gene therapy (CGT) is a patient waiting for something more—more time, more hope, more options. These are not abstract innovations; they’re breakthroughs with the power to change lives.”



U.S. Pipeline for Cell and Gene Therapy

Riding the next wave of innovation in cell and gene therapy

The CGT landscape is continuing to advance quickly, but not always predictably. While scientific progress continues across multiple disease areas, recent market shifts and regulatory changes have introduced new layers of complexity, but also new opportunities. CGT has always been a high-stakes field, but today, it's more complex and consequential than ever.

The 2024 report highlighted a flourishing CGT pipeline and growing momentum in FDA approvals, pointing to what many predicted would be a boom in approved therapies. Over the past 12 months, scientific progress has continued—and even accelerated—in some areas. Many programs remain in early stages, but recent data from late-stage trials point to potentially game-changing advances, particularly in disease areas where there have historically been few effective treatment options.

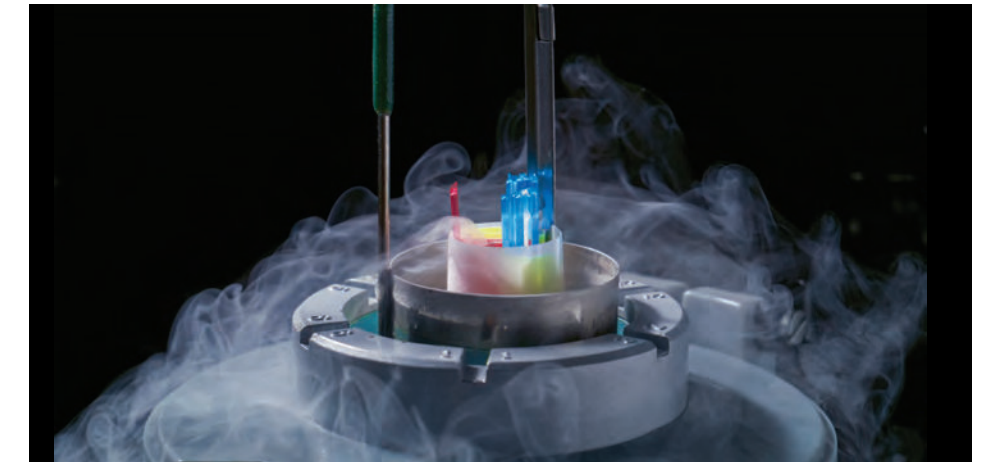
The breadth and depth of the CGT pipeline remain a powerful signal of continued innovation across a range of diseases. A total of 178 new oncology-focused CGT drug candidates entered the late-stage pipeline in the past year alone: a strong indicator of both clinical advancement and sustained investment in cancer research. Within this group, we're seeing innovation in areas such as dual-target CAR T-cell therapies, which have shown early but encouraging results in multiple myeloma and large B-cell lymphoma.^{1,2}

Looking beyond oncology, scientific innovation continues to gain ground in disease areas with wider patient populations, suggesting that CGT may have a broader impact on patients in the years to come. Since the first reports of clinical remission in severe lupus patients treated with CAR T-cell therapy in 2022, multiple agents are now in clinical development, with early readouts demonstrating

promising remission rates and reduced disease activity.^{3,4} A similar wave of innovation is reaching diabetes, where researchers are pursuing ways to restore insulin production, and early efforts are yielding encouraging results.⁵

Policymakers and regulators have also signaled strong support for innovation. The FDA recently opened its Commissioner's National Priority Voucher (CNPV) pilot program, a new initiative designed to accelerate regulatory reviews for therapies that align with key U.S. health priorities.⁶ Under the program, eligible products like CGTs could receive reviews in as little as one to two months. Additionally, the recent RDEP proposal could accelerate approvals of gene therapies for ultra-rare diseases.⁷ These programs reflect the agency's growing focus on expediting access to innovative, high-impact therapies.

However, this progress has not come without uncertainty. Headlines about potential safety issues with certain therapies have raised questions about consistency in the approval process, especially for therapies cleared under accelerated review. Growing scrutiny of regulatory frameworks prompted some industry leaders to re-evaluate the path to market. In addition, according to the Alliance for Regenerative Medicine (ARM), CGT sector investments from July 2024 to July 2025 are tracking at



roughly half the pace of the previous year, reflecting a more cautious investment climate.⁸

To better understand how these dynamics are shaping the future of CGT, this year's report includes a year-over-year comparison of the late-stage U.S. pipeline. While only a handful of CGTs have been approved by the FDA so far in 2025, the pipeline itself is still growing. Oncology continues to dominate the category, driven in part by expanding applications with 461 unique drugs in solid tumors, which added nine new candidates to the late-stage pipeline this year.

The pipeline also reflects continued advancement of CGT science in high-prevalence areas, such as diabetes, congestive heart failure, and autoimmune diseases. This points to the pipeline's evolution

from one focused on rare diseases to one that can potentially support better outcomes for broader patient populations.

While it may take time to fully understand the downstream effects of recent policy changes and market shifts, the pipeline data tell a clear story: scientific innovation in CGT remains robust, with strong momentum in oncology and new inroads into chronic and complex diseases.

The following section explores these pipeline trends in greater depth, along with insights from Navneet Majhail, MD, physician-in-chief of blood cancers at the Sarah Cannon Cancer Network. Dr. Majhail shares his perspective on what this evolving pipeline means for clinical trial recruitment, site readiness, and the implications for patients, providers, and manufacturers. ●

FDA-approved cell and gene therapies (CGTs)^{1,2}

The pace of approvals of new CGTs has slowed since our last report.

THERAPIES APPROVED SINCE OCTOBER 2024

Cell Therapies ^A				
PRODUCT	COMPANY	MODALITY	DISEASE AREA(S)	APPROVAL DATE
PROVENGE	Dendreon Pharmaceuticals LLC. ^B	Cell	Prostate cancer	April 29, 2010
KYMRIAH	Novartis Pharmaceuticals Corporation	Cell	Acute lymphoblastic leukemia; large B-cell lymphoma; follicular lymphoma	August 30, 2017
YESCARTA	Kite, A Gilead Company ^C	Cell	Large B-cell lymphoma; follicular lymphoma	October 18, 2017
TECARTUS	Kite, A Gilead Company ^C	Cell	Mantle cell lymphoma; acute lymphoblastic leukemia	July 24, 2020
BREYANZI	Juno Therapeutics, Inc., a Bristol Myers Squibb Company ^D	Cell	Large B-cell lymphoma; chronic lymphocytic leukemia; follicular lymphoma; mantle cell lymphoma	February 5, 2021
ABECMA	Bristol Myers Squibb ^E	Cell	Multiple myeloma	March 26, 2021
CARVYKTI	Johnson & Johnson & Legend Biotech ^F	Cell	Multiple myeloma	February 28, 2022
OMISIRGE	Gamida Cell Inc.	Cell	Hematologic malignancies	April 17, 2023
LANTIDRA	CellTrans Inc.	Cell	Type 1 diabetes	June 28, 2023
AMTAGVI	Iovance Biotherapeutics, Inc.	Cell	Melanoma	February 16, 2024
TECELRA	US WorldMeds ^G	Cell	Synovial sarcoma	August 1, 2024
AUCATZYL	Autolus, Inc.	Cell	Acute lymphoblastic leukemia	November 8, 2024
RYONCIL	Mesoblast, Inc.	Cell	Graft versus host disease (GVHD)	December 19, 2024

LAVIV is excluded from this list as our research indicates the product is no longer commercially available.

^A Cell Therapies includes gene-modified cell therapies.

^B At the time of approval, the manufacturer was listed as Dendreon Corp.

^C At the time of approval, the manufacturer was listed as Kite Pharma, Inc.

^D At the time of approval, the manufacturer was listed as Juno Therapeutics, Inc.

^E At the time of approval, the manufacturer was listed as Celgene Corporation, a Bristol-Myers Squibb Company.

^F At the time of approval, the manufacturer was listed as Janssen Biotech, Inc.

^G At the time of approval, the manufacturer was listed as Adaptimmune LLC.

Tissue-Engineered Products				
PRODUCT	COMPANY	MODALITY	DISEASE AREA(S)	APPROVAL DATE
MACI	Vericel Corporation	Tissue-engineered products	Cartilage defects of the knee	December 13, 2016
STRATAGRAFT	Stratatech Corporation, a Mallinckrodt Company ^H	Tissue-engineered products	Thermal burns	June 15, 2021
RETHYMIC	Sumitomo Pharma Co., Ltd. ^I	Tissue-engineered products	Immune reconstitution in patients with congenital athymia	October 8, 2021
SYMVESS	Humacyte Global, Inc.	Tissue-engineered products	Extremity arterial injury	December 19, 2024

GINTUIT is excluded from this list as our research indicates the product is no longer commercially available.

^H At the time of approval, the manufacturer was listed as Stratatech Corporation.

^I At the time of approval, the manufacturer was listed as Enzyvant Therapeutics GmbH.

Gene Therapies				
PRODUCT	COMPANY	MODALITY	DISEASE AREA(S)	APPROVAL DATE
IMLYGIC	BioVex LLC., a subsidiary of Amgen Inc.	Gene	Melanoma	October 27, 2015
LUXTURNA	Spark Therapeutics, Inc. & Novartis Pharmaceuticals Corporation ^J	Gene	Biallelic RPE65 mutation-associated retinal dystrophy	December 19, 2017
ZOLGENSMA	Novartis Pharmaceuticals Corporation	Gene	Spinal muscular atrophy (SMA)	May 24, 2019
ZYNTEGLO	Genetix Biotherapeutic ^K	Gene	β-thalassemia	August 17, 2022
SKYSONA	Genetix Biotherapeutics ^K	Gene	Active cerebral adrenoleukodystrophy (CALD)	September 16, 2022
HEMGENIX	uniQure, Inc. and CSL Behring LLC	Gene	Hemophilia B	November 22, 2022
ADSTILADRIN	Ferring Pharmaceuticals Inc.	Gene	Bladder cancer	December 16, 2022
VYJUVEK	Krystal Biotech, Inc.	Gene	Dystrophic epidermolysis bullosa (DEB)	May 19, 2023
ELEVIDYS	Sarepta Therapeutics, Inc.	Gene	Duchenne muscular dystrophy	June 22, 2023
ROCTAVIAN	BioMarin Pharmaceutical, Inc.	Gene	Hemophilia A	June 29, 2023
LYFGENIA	bluebird bio, Inc.	Gene	Sickle cell disease	December 8, 2023
CASGEVY	Vertex Pharmaceuticals Incorporated & Crispr Therapeutics ^L	Gene	Sickle cell disease and β-thalassemia	December 8, 2023
LENMELDY	Orchard Therapeutics	Gene	Metachromatic leukodystrophy (MLD)	March 18, 2024
KEBILIDI	PTC Therapeutics, Inc.	Gene	Aromatic L-amino acid decarboxylase (AADC) deficiency	November 13, 2024
ENCELTO	Neurotech Pharmaceuticals, Inc.	Gene	Idiopathic macular telangiectasia type 2 (MacTel)	March 5, 2025
ZEVASKYN	Abeona Therapeutics, Inc.	Gene	Recessive dystrophic epidermolysis bullosa (RDEB)	April 28, 2025
PAPZIMEOS	Precigen, Inc.	Gene	Recurrent respiratory papillomatosis	August 14, 2025

BEQVEZ is excluded from this list as our research indicates the product is no longer commercially available.

^J Since approval, Novartis announced a licensing agreement with Spark Therapeutics covering development, registration and commercialization rights to voretigene neparvovec in markets outside the US.

^K At the time of approval, the manufacturer was listed as bluebird bio Inc.

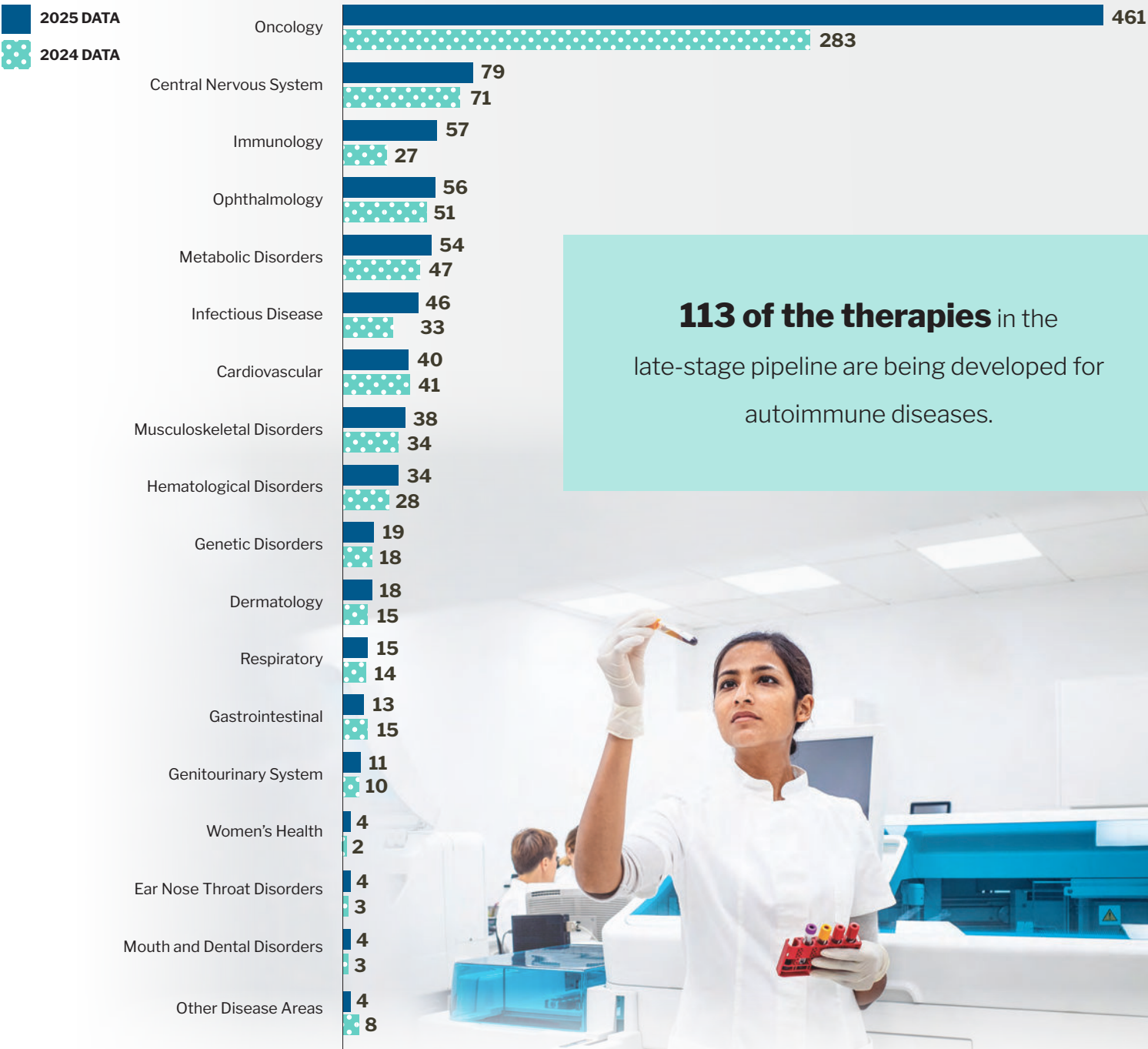
^L At the time of approval, the manufacturer was listed as Vertex Pharmaceuticals Inc.

Cord Blood Cell Therapies				
PRODUCT	COMPANY	MODALITY	DISEASE AREA(S)	APPROVAL DATE
HEMACORD	New York Blood Center, Inc.	Cell	Disorders affecting the hematopoietic system	November 10, 2011
HPC, Cord Blood	Clinimmune Labs, University of Colorado Cord Blood Bank	Cell	Disorders affecting the hematopoietic system	May 24, 2012
ALLOCORD	SSM Cardinal Glennon Children's Medical Center	Cell	Disorders affecting the hematopoietic system	May 30, 2012
DUCORD	Duke University School of Medicine	Cell	Disorders affecting the hematopoietic system	October 4, 2012
HPC, Cord Blood, Life South	LifeSouth Community Blood Centers, Inc.	Cell	Disorders affecting the hematopoietic system	June 13, 2013
HPC, Cord Blood, Bloodworks	Bloodworks	Cell	Disorders affecting the hematopoietic system	January 28, 2016
CLEVECORD	Cleveland Cord Blood Center	Cell	Disorders affecting the hematopoietic system	September 1, 2016
HPC, Cord Blood, MD Anderson	MD Anderson Cord Blood Bank	Cell	Disorders affecting the hematopoietic system	June 21, 2018
REGENECYTE	StemCyte, Inc.	Cell	Disorders affecting the hematopoietic system	November 20, 2024

Oncology continues to dominate the CGT pipeline, but other indications are emerging.

Late-stage CGTs in U.S. pipeline by therapy area

Total number of unique drugs in the 2025 pipeline is 845. Some drugs are represented in multiple therapy areas.



Source: GlobalData Filtered Drug Database (Q1 24, Q1 25)

This pipeline analysis focuses exclusively on cell and gene therapies and excludes other advanced modalities such as RNA-based treatments and antisense oligonucleotide therapies. The pipeline data from the 2024 Cell and Gene Therapy Report has been recalculated to align with this criteria.

Glossary of terms

PIPELINE CHARTS

CGT Defining Criteria

Cell, gene, and gene-modified cell therapies are defined by parameters set forth by the Alliance for Regenerative Medicine (ARM), an international advocacy organization dedicated to realizing the promise of regenerative medicines and advanced therapies.

- For the purposes of this pipeline analysis, the following therapy types and categories are excluded: cell therapies without engineering modifications, therapies involving scaffolding, therapies with sustained or self-perpetuating gene modifications, and other advanced modalities such as RNA-based treatments and antisense oligonucleotide therapies.

Cell Therapy

Cell therapy is the administration of cells into a patient's body as a therapy to treat a disease. This includes administration of autologous (from the patients themselves) or allogeneic (from another human being) cells. Cell therapy incorporates cells that have been substantially manipulated chemically or physically or cells that are not intended to be used for the same essential functions in the body.

Gene Therapy

A therapy in which foreign genetic material is inserted into a person's cells to prevent or fight disease.

Gene-Modified Cell Therapy

In gene-modified cell therapy, specific cells are genetically modified outside the body and placed into the patient's body in order to help the patient fight a disease. These cells may be autologous or allogeneic.

Source: GlobalData

Allogeneic

A type of cell therapy in which the therapeutic cells are derived from a different person than the intended recipient. The donor cells are cultured, modified, and then administered to the patient's body.

Autologous

A type of cell therapy in which the therapeutic cells are derived from the patient who is undergoing treatment. The cells are cultured, modified, and then re-infused into the patient from whom they were derived.

Late-stage U.S. Pipeline

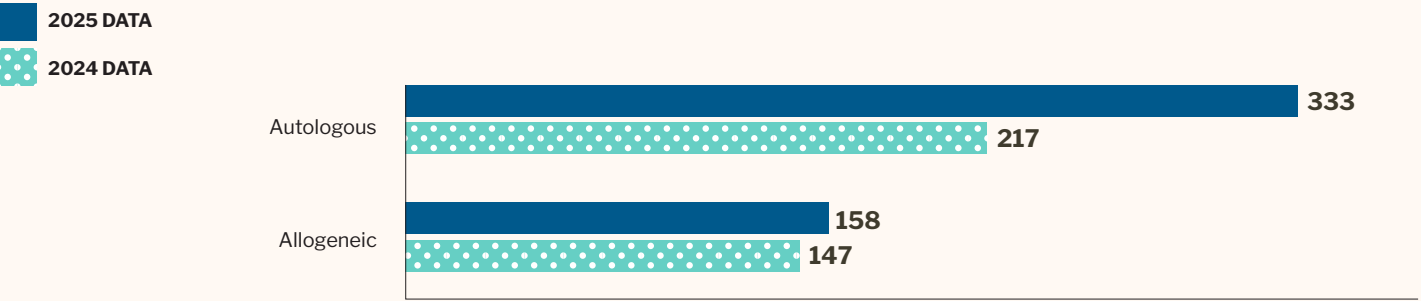
Drugs in development in the U.S. and/or Global geographies in Phase 2 or Phase 3, or Pre-Registrational, based on public data. The pipeline drug geography "Global" is a geographical placeholder that is tagged to pipeline drugs where the company or institution has not yet specified the exact geographical region or country in which they intend to pursue market approval.



Growth in the development of autologous therapies continues to outpace allogeneic therapies.

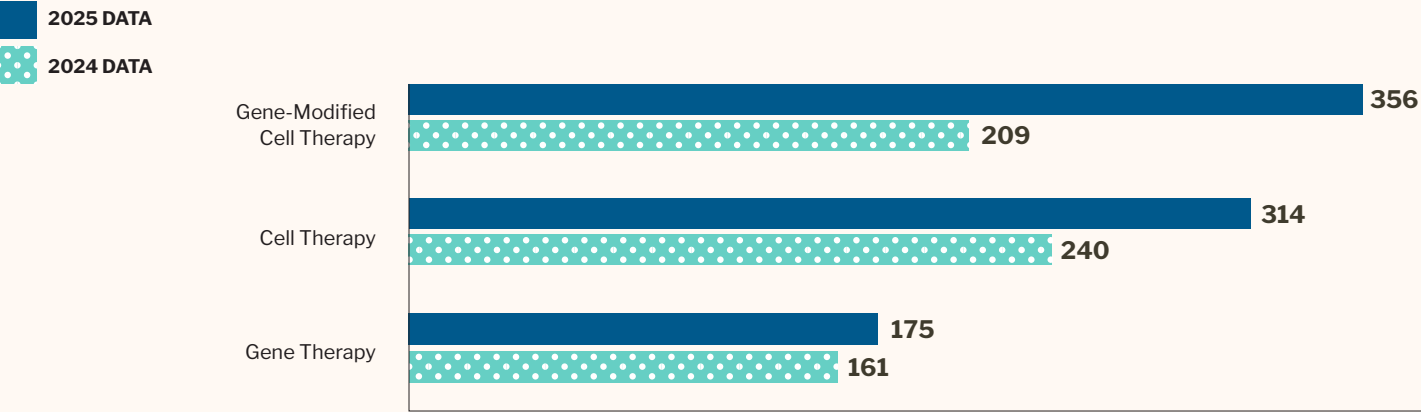
Late-stage CGTs in U.S. pipeline: by autologous or allogeneic type*

491 out of the 845 CGT late-stage pipeline drugs in the database are tagged as autologous or allogeneic.



*GlobalData classifies these labels as "Molecule Type." Only 491 out of 845 unique drug database records have an autologous/allogeneic designation. Others are unknown at this time.
Source: GlobalData Filtered Drug Database (Q1 24, Q1 25)

Late-stage CGTs in U.S. pipeline: by cell, gene, or gene-modified cell therapy (GMCT)

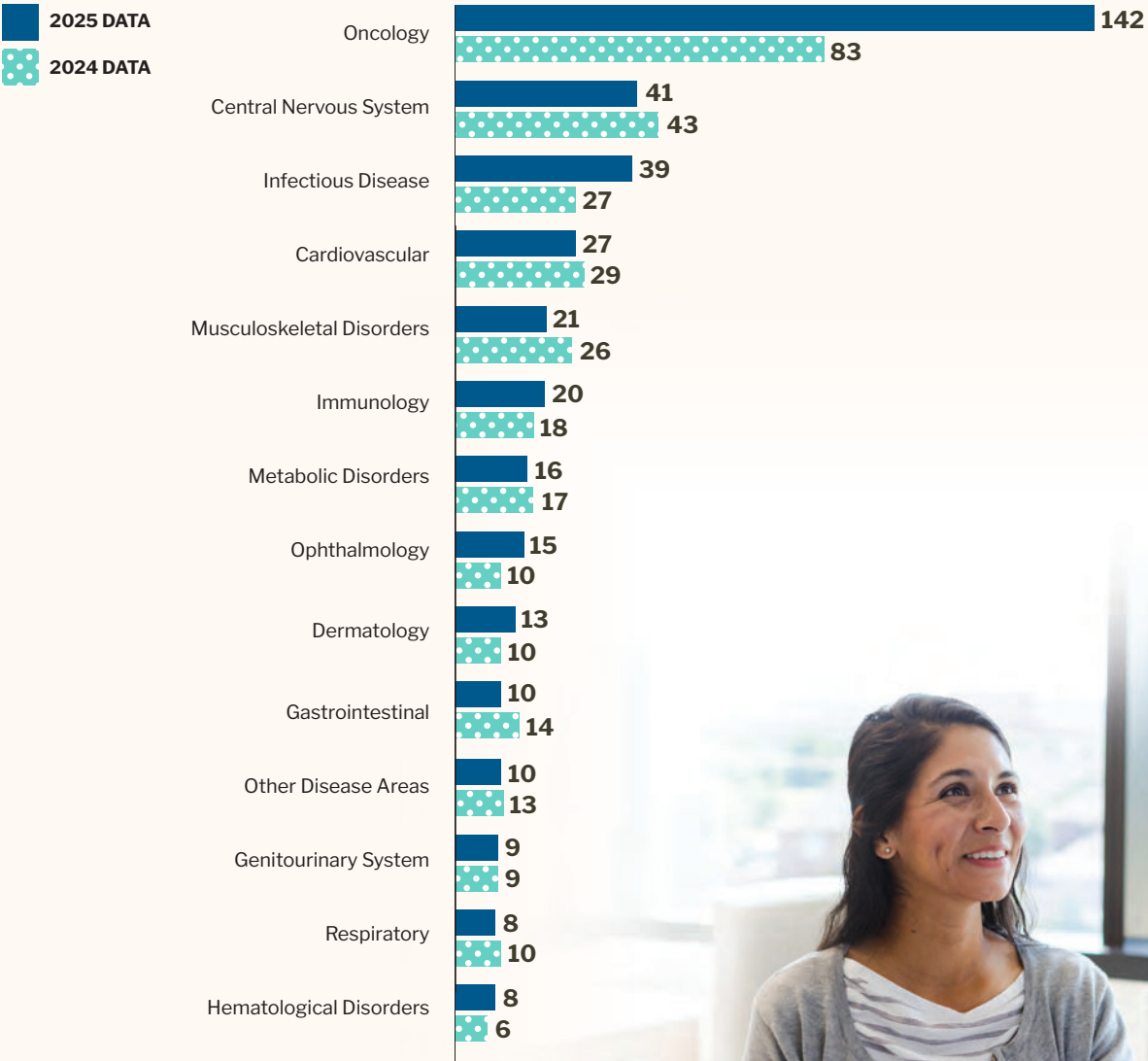


Source: GlobalData Filtered Drug Database (Q1 24, Q1 25)

Therapies for infectious disease, central nervous system, and cardiovascular disorders represent a growing portion of the cell therapy pipeline.

Late-stage cell therapies in U.S. pipeline by therapy area

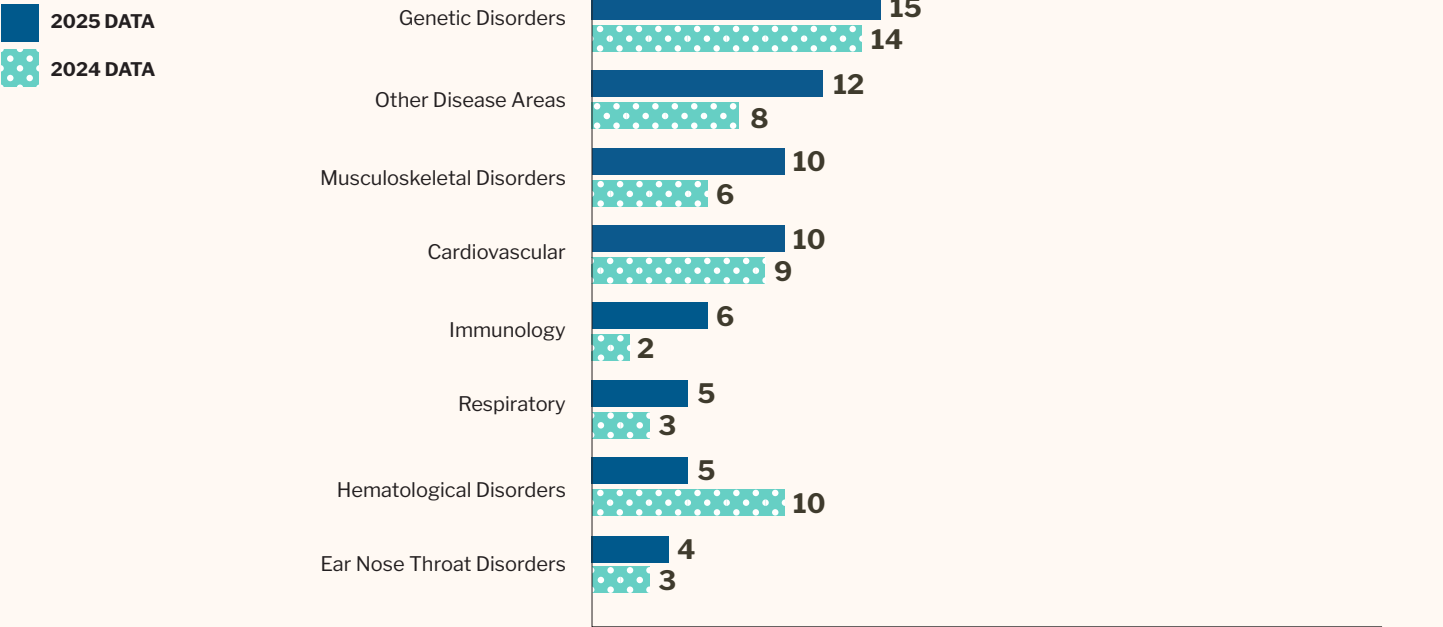
Total unique drugs is 314. Some drugs are represented in multiple therapy areas.



Source: GlobalData Filtered Drug Database (Q1 24, Q1 25)

Late-stage gene therapies in U.S. pipeline by therapy area

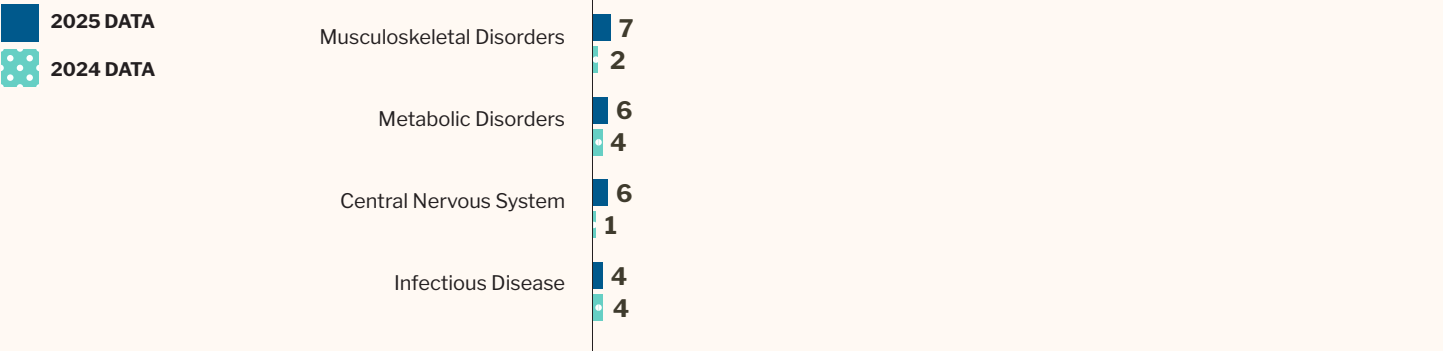
Total unique drugs is 175. Some drugs are represented in multiple areas.



Source: GlobalData Filtered Drug Database (Q1 24, Q1 25)

Late-stage GMCTs in U.S. pipeline by therapy area

Total unique drugs is 356. Some drugs are represented in multiple areas.



Source: GlobalData Filtered Drug Database (Q1 24, Q1 25)

Expert perspective: NAVNEET MAJHAIL, MD

Clinical trial recruitment faces new challenges as CGT market matures

Less than a decade after the first cell and gene therapies (CGTs) were approved by the FDA, the treatment landscape has fundamentally shifted. Patients who have had few or no medicines to treat serious and life-threatening conditions can now choose between commercially available drugs or a range of clinical trials with new treatments.

This evolution presents new challenges for biopharma companies trying to recruit patients and sites for clinical trials. At Sarah Cannon Cancer Network, which operates one of the largest cell and gene therapy programs in the country, the shift is dramatic, said Navneet Majhail, MD, Physician-in-Chief of Blood Cancers at the organization. Through 2022, nearly three-quarters of patients receiving CAR T therapies were enrolled in clinical trials, which are supported by Sarah Cannon Research Institute, while one quarter were on commercial therapy. Today, that ratio has flipped.

The change reflects the success of the CAR T field in moving from experimental to standard care. But it also means companies developing new therapies must work harder to demonstrate why patients should choose an investigational treatment over proven alternatives.

For major cancer centers like Sarah Cannon, which performed more than 1,500 transplants and cell therapies last year, the challenge extends beyond patient recruitment to managing an increasingly broad portfolio of both clinical trials and commercial therapies, while ensuring that each patient gets the treatment that is best for them.

Barriers Standing in the Way
Majhail said there are four main categories of obstacles that compound

the difficulty of running effective cell and gene therapy trials.

Patient-level barriers remain one of the most fundamental hurdles. Geographic distance to specialized centers, insurance coverage gaps, and socioeconomic factors create the same access problems that have long plagued clinical trials. But CGTs add layers of complexity.

“These CGTs are available at specialized centers with the right expertise, the infrastructure, the people, the capacity and everything else,” Majhail said. “Sometimes people travel a couple of hours to get there for treatment, and if a trial requires you to come back every so often or live close by for a certain amount of time, there can be those geographic barriers.”

The second challenge involves investigators themselves. Unlike traditional cancer trials where virtually any oncologist might enroll patients, CGTs require specialized expertise that is still relatively scarce, given the recent rapid growth of the CGT space.

“The way these therapies are and where they’re heading, it’ll be hard for just one person to know it all and do it well,” Majhail said. “You need to have collaborative multidisciplinary teams that come together to offer these therapies collectively.”

Health center capacity is the third bottleneck. Even experienced programs face constraints as they juggle increasing numbers of commercial treatments and competing clinical trials.

The fourth barrier involves the products themselves—manufacturing timelines, supply chain requirements, and slot availability that can add complexity, even when patients and treatment centers are prepared and willing.



“It’s about the team—setting up the right team to both facilitate opening a trial, enrolling patients on them, and then supporting patients as they go through the process.”

— Navneet Majhail, MD
Physician-in-Chief of Blood Cancers
at Sarah Cannon Cancer Network

When Protocols Meet Reality

Majhail says there are often disconnects between how clinical trials are designed and how they work in practice that can make it more difficult to operate successfully. He points to examples where well-intentioned protocols create operational challenges for the centers trying to implement them.

“Sometimes these trials come through and we are like, you wrote this whole protocol, got it through FDA, but I’m not sure you had a cell therapy expert actually take a look at this and ask, ‘is this even workable?’” Majhail said.

The problems range from basic logistics to patient experience. Some protocols specify product shipping or storage requirements that don’t align with how hospitals actually handle cell therapies. Others demand that patients spend



many hours in clinic for outpatient procedures, which can deter some patients from signing up for a trial and present scheduling conflicts for hospital staff.

“You want to push something in the outpatient setting, but you’re asking the patient to be there for 10 hours of the day. How do you make that work in a clinic?” Majhail said.

The disconnect becomes more costly as competition intensifies. Sites have limited capacity and multiple trial options, making operational feasibility a key factor in which studies they choose to support.

Building Trials That Work

Despite the challenges, Majhail said there are three key strategic approaches that can help CGT clinical trials succeed.

The foundation starts with assembling the right team at clinical sites. This goes beyond finding qualified investigators to building entire support structures that can handle the complexity of CGT trials.

“It’s about the team—setting up the right team to both facilitate opening a trial, enrolling patients on them, and then supporting patients as they go through the process,” Majhail said.

The second element involves fostering a research culture that views clinical trials as potentially the best treatment option for patients, not just an alternative when commercial therapies fail.

“You can open as many trials as you want, but if there’s not a culture that facilitates or encourages looking at research clinical trials, which I think most of us agree is the best therapy for patients, then it’s not going to happen,” he said.

The third recommendation addresses the protocol design problems directly. Majhail urges companies to partner with experienced centers early in clinical development to ensure trials integrate smoothly into real-world workflows.

For companies entering the field, this means engaging with treatment centers not just as trial sites, but as partners in designing studies that can be implemented successfully.

The Autoimmune Challenge Ahead

As CGTs expand beyond cancer into broader areas, such as autoimmune disease, Majhail expects fundamentally different approaches to patient management and trial design will be required.

While cancer patients typically remain within oncology teams throughout their treatment journey, autoimmune patients will need coordination with rheumatologists, neurologists, and other specialists who haven’t traditionally worked with cell therapy centers. It also means understanding that patients have different risk-value calculations to make. For example, side effects that cancer patients might accept as necessary trade-offs could carry different weight for autoimmune patients with well-controlled conditions.

“For many of our cancer patients, if you lose your hair, it’s kind of almost expected as you go,” Majhail said. “But to say to a young woman with lupus, you’re going to lose your hair with this, but you’ve got these other therapies. I think these are some risk-benefit conversations that’ll be very interesting in that setting.”

Working Through Real-World Pain Points

As competition for clinical trial participants intensifies, Majhail’s advice for the industry focuses on bridging the gap between laboratory innovation and clinical reality. Companies that understand operational challenges early will have advantages in recruiting both sites and patients.

This collaboration needs to start during protocol development, not after FDA approval.

“Working with experienced centers and people who’ve done this is important as you’re trying to think about commercializing your therapy,” he said. By working together to eliminate real world pain points for patients, physicians and treatment centers, “that gets everyone to a happy place.” he said. ●

Provider Perspectives: Challenges and Opportunities in CGT

Delivering on CGT’s promise amid persistent access challenges

Although one of the key themes of our 2025 report is the expansion of CGT into new therapeutic areas, oncology still dominates the field today. With the majority of approved therapies used to treat hematologic cancers, oncologists remain on the frontlines of CGT delivery with more direct experience than physicians in any other specialty.

To capture their perspectives, we conducted a double-blind survey of 125+ oncologists across the U.S. for the second consecutive year. Respondents reflected a wide range of geographies, care settings, and experience levels, but all had direct involvement in referring or treating patients with CGTs.

Last year’s results showed clear optimism among providers about the future of CGT, and that optimism has held

steady—but so have the barriers. One year later, our latest findings show that oncologists continue to believe in the long-term potential of CGTs, yet remain frustrated by the lack of commercial patient volume and the slow progress in addressing persistent access challenges.

Despite these hindrances, there are meaningful signs of progress in how, overall, experience with CGT continues to grow. In this year’s survey, 60% of physicians said they are “very familiar” with CGTs, up 5% from last year. The number of physicians in our survey treating patients with CGTs increased from 55% in 2024 to 64% today. Among those who treat patients with these therapies, the average number of patients treated per year increased from 17 to 25, suggesting increased



institutional readiness and growing comfort with these therapies in clinical practice.

Still, obstacles remain, notably in the lack of long-term outcomes data. “Convincing durability of data” continues to be ranked by oncologists as one of the top barriers to expanding CGT access. In 2025, 66% of respondents said their patients view CGTs as “too experimental,” up from 45% in 2024. Furthermore, two-thirds (65%) of surveyed oncologists still view CGTs as “largely unproven,” a finding consistent with last year’s results. These perceptions reflect the tension between accelerating adoption and the reality that these therapies are still new and typically lack durability data.

While the need to expand CGT care into community settings is gaining traction, challenges around site-of-care readiness are persistent among providers in community-based hospitals and clinics. Compared to last year, respondents were twice as likely to agree that simplifying the process to become a qualified treatment center should be a top priority. Among community-based providers, 46% cited this as an urgent need to improve access to CGT. However, only half (50%) of community oncologists said they feel ready to embrace CGT innovations in the next decade, compared to two-thirds (67%) of oncologists practicing at larger academic centers. Among community oncologists whose institutions are not currently administering CGTs, only one-third (35%) expect their sites to become qualified treatment centers in the next four years.

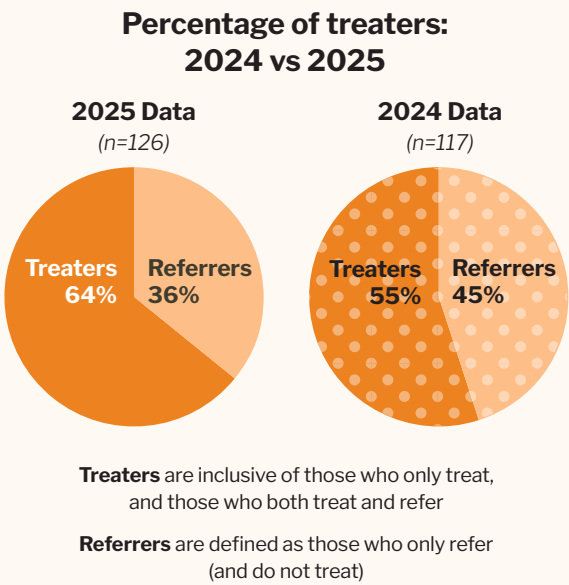
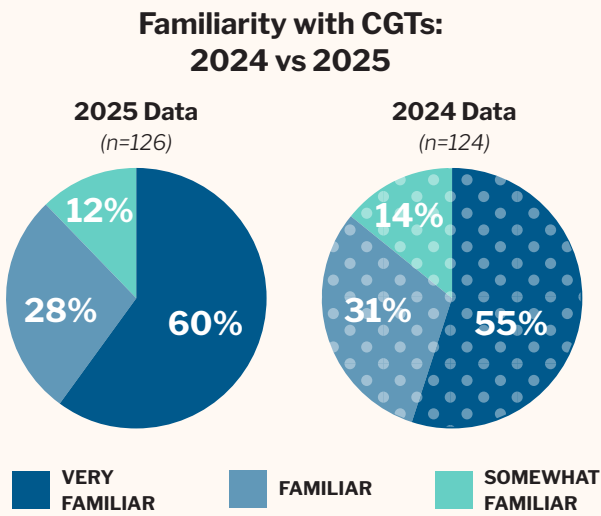
Financial and reimbursement concerns remain the most commonly cited barrier to care. About three-quarters (72%) of physicians said insurance coverage is the top reason patients who are referred for CGT ultimately do not receive it. In this year’s survey, more respondents said they believe the U.S. healthcare system is fundamentally misaligned with the requirements of CGT delivery. However, there’s optimism that alternative payment models may eventually pave the way for broader access and more equitable reimbursement.

In many ways, this year’s findings mirror those of our 2024 survey, reinforcing that while provider confidence in CGTs remains high, real-world progress in removing structural and financial barriers has been slow.

In the following section, we explore these challenges in greater depth. We share new quantitative findings from the 2025 survey, alongside qualitative insights from two leaders on the front lines of CGT care. Mylove Mortel, Director of Transplant, Cellular Therapy and Advanced Hematology at University of Chicago Medicine, shares her perspective on how large institutions are preparing for a coming wave of CGTs in expanded disease areas. Ivan Borrello, MD, a hematologist oncologist at Tampa General Hospital, offers strategies for how community-based hospitals can overcome access barriers and play a greater role in the future of CGT delivery. Together, these insights provide a clearer picture of where we stand today and what’s needed to move forward tomorrow. ●



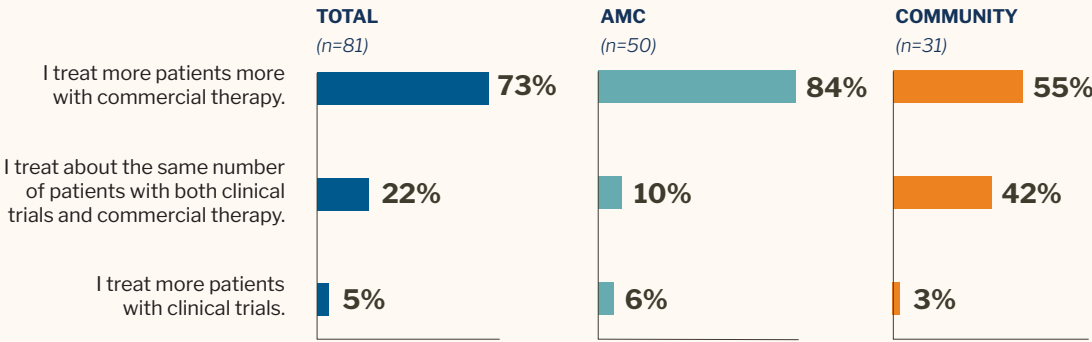
Experience and familiarity treating patients with CGTs has increased in the past year.



Physicians treated an average of **25 patients** with CGTs in 2025 versus an average of only **17 patients** in 2024



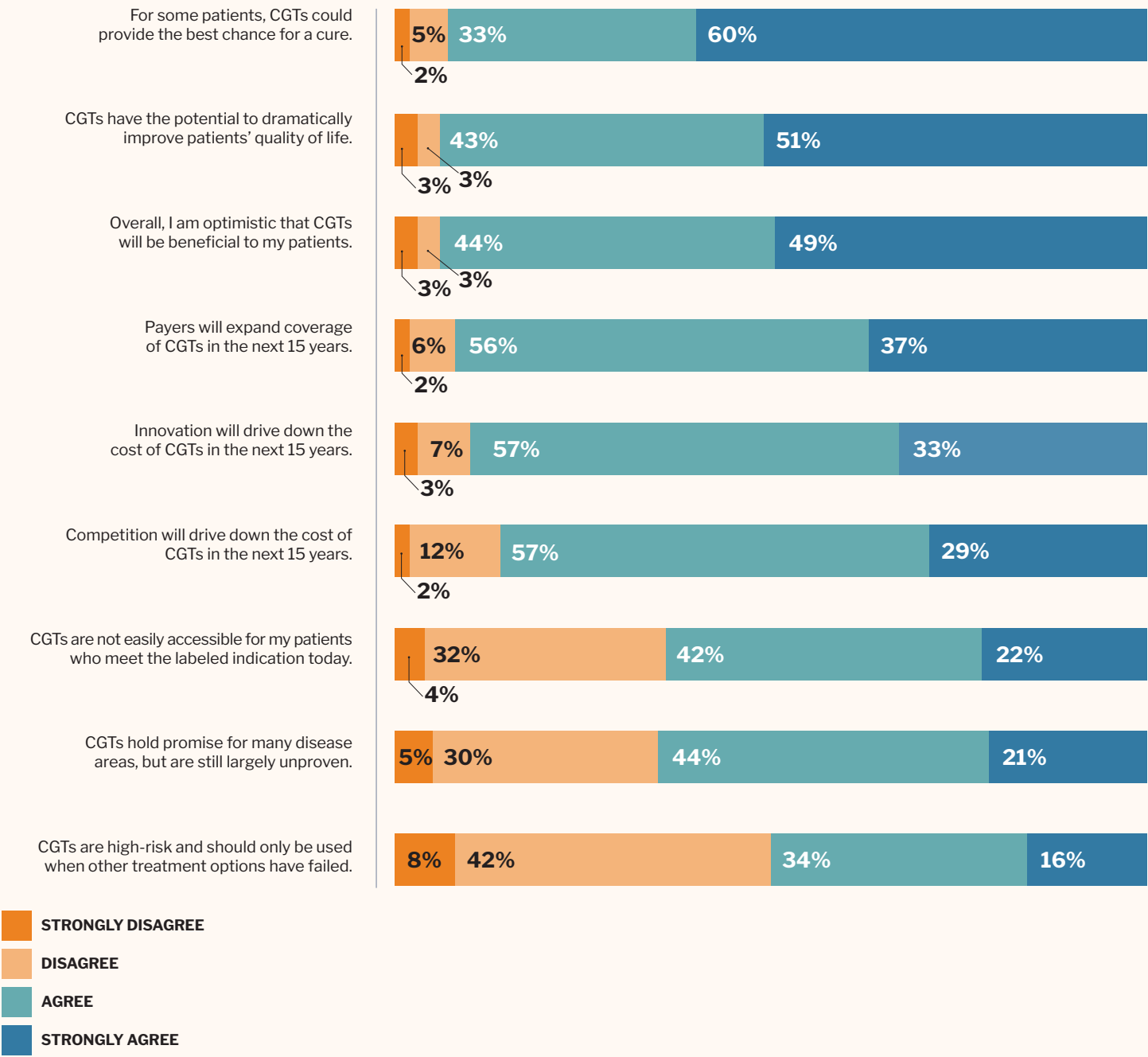
Of the patients you treat with CGTs, do you treat more patients with CGTs via clinical trials or via commercial therapy?



Strong majority of oncologists say CGTs provide the best chance for a cure, but two-thirds say they are unproven and half say they are high risk.

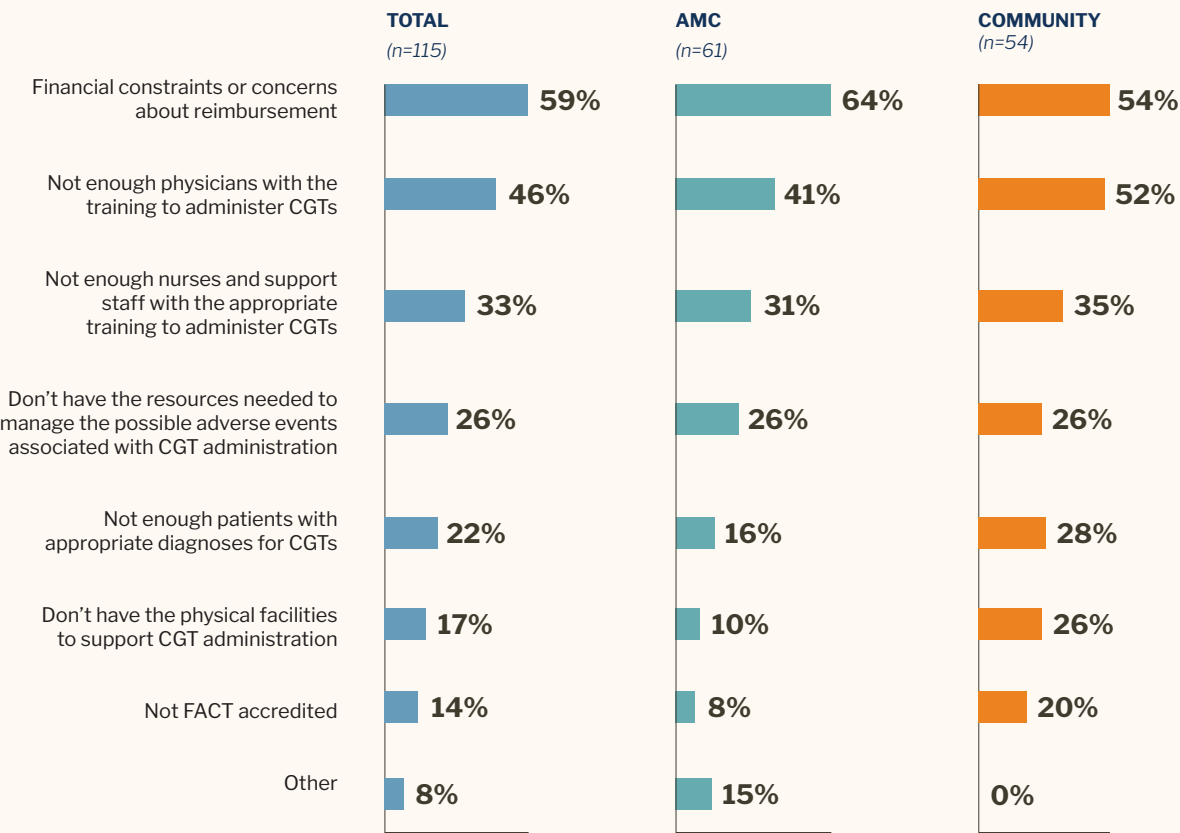
To what extent do you agree or disagree with the following?

All Respondents (n=126)



Financial constraints and reimbursement concerns are the top barriers limiting CGT administration.

What are the barriers limiting your institution's ability to administer CGTs?

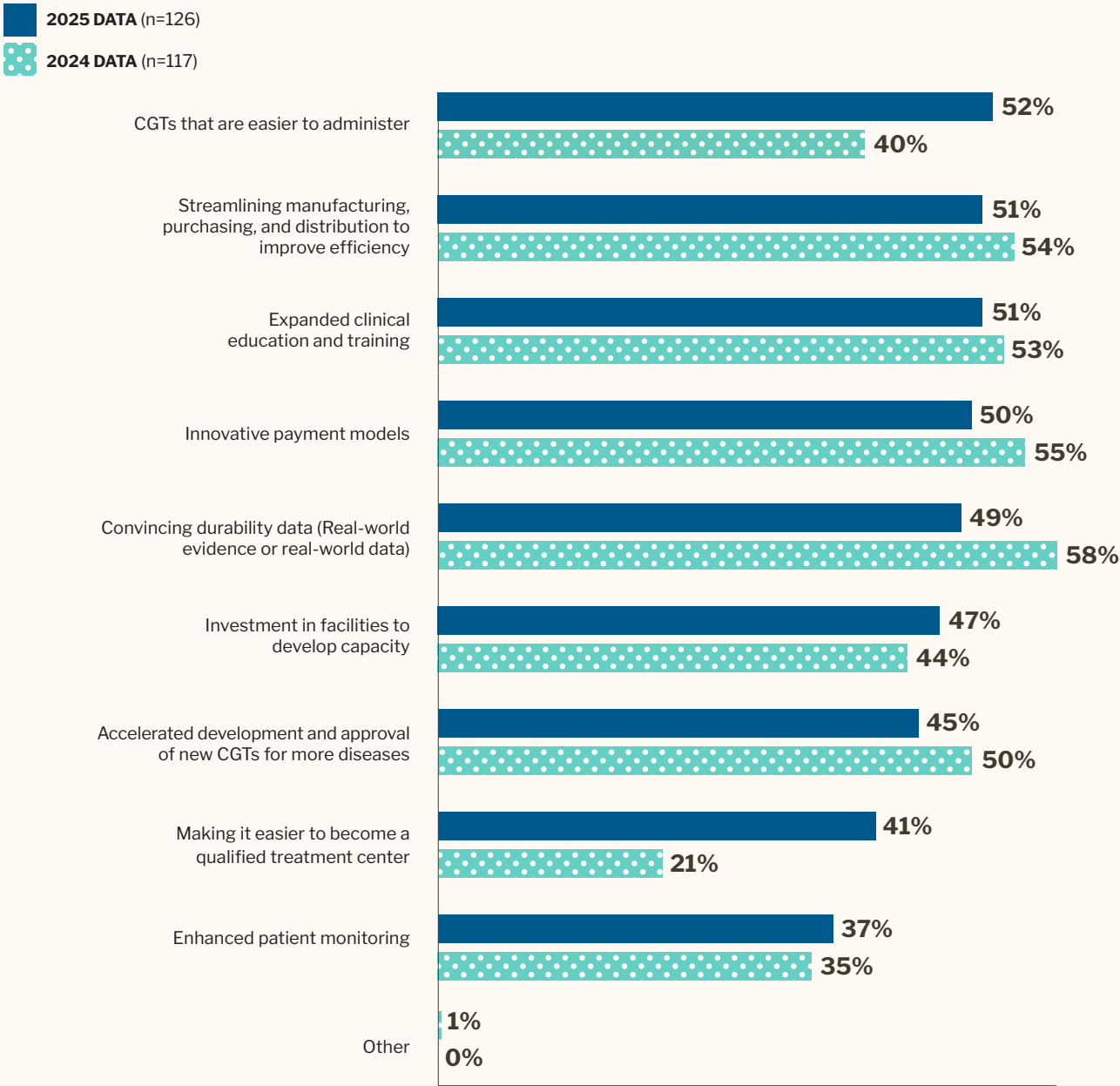


More oncologists from community settings (26%) than those from AMCs (10%) say they “don’t have the physical facilities to support CGT administration.”

Oncologists from the community (20%) are more likely to report FACT accreditation as an institutional barrier to CGT administration compared to those in AMCs (8%).

In 2025, twice as many oncologists said making it easier to become a qualified treatment center should be prioritized.

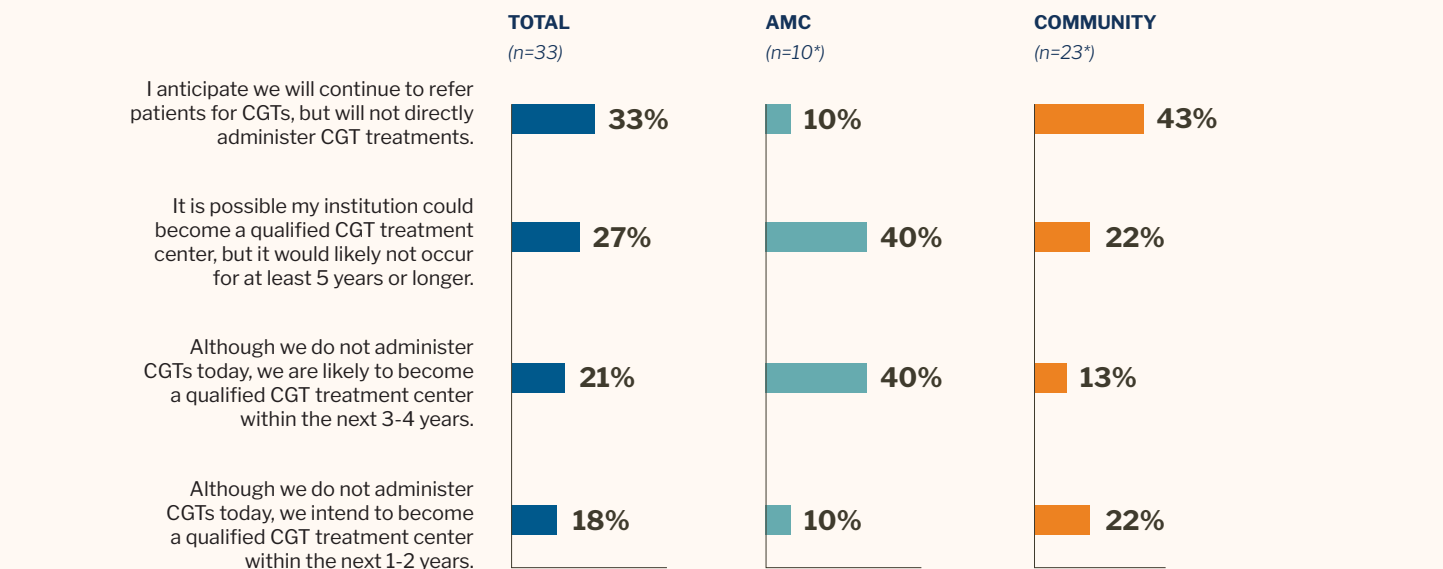
Thinking about CGTs across all care settings (and excluding the topic of overall costs), which of the following needs to be prioritized in the next decade to increase access to CGTs?



Only 1 in 4 oncologists who don't provide CGT care today expect to become qualified in the next 4 years.

Which best describes your institution's future outlook when it comes to CGT administration?

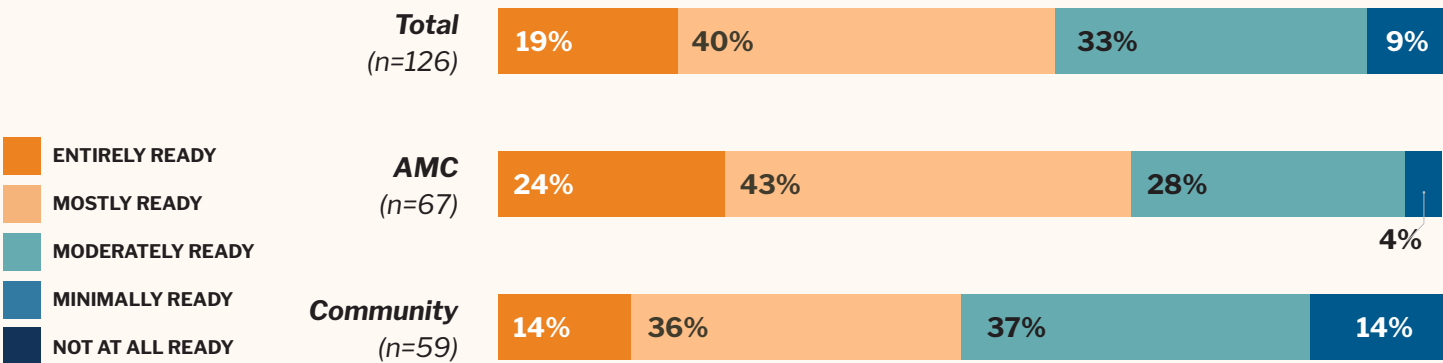
(Respondents include those whose institutions do not currently offer CGTs.)



*Small Base Size

Two-thirds of oncologists in AMCs feel ready to embrace CGTs vs. only half of community oncologists.

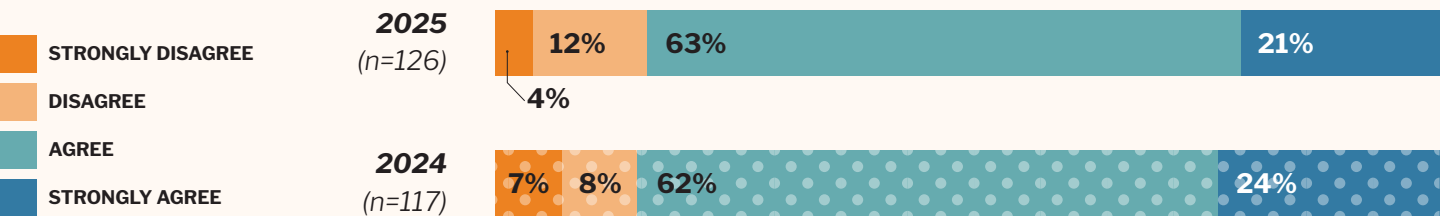
Please rank your readiness to embrace these innovations from a scale of 1 to 5, with 1 being not ready at all and 5 being entirely ready.



4 in 5 oncologists say CGTs are incompatible with the U.S. healthcare system—but optimism about innovative payment models continues.

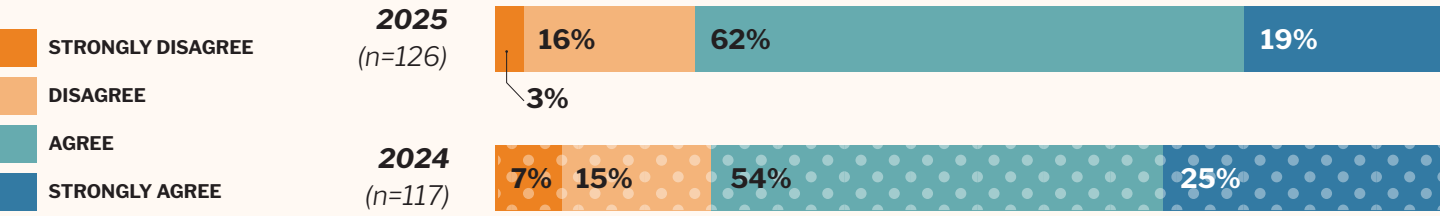
How much do you agree or disagree with the following statement:

Innovative payment models will lead to broader adoption of CGTs.



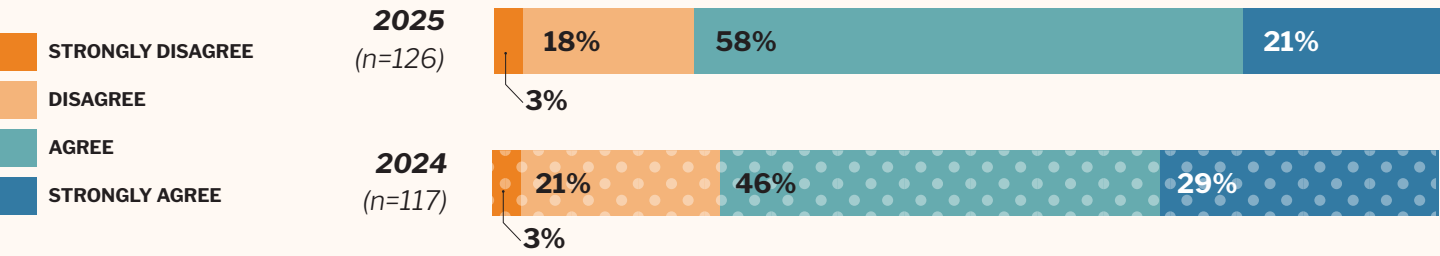
How much do you agree or disagree with the following statement:

Innovative payment models are likely to help alleviate disparities in access to treatment.



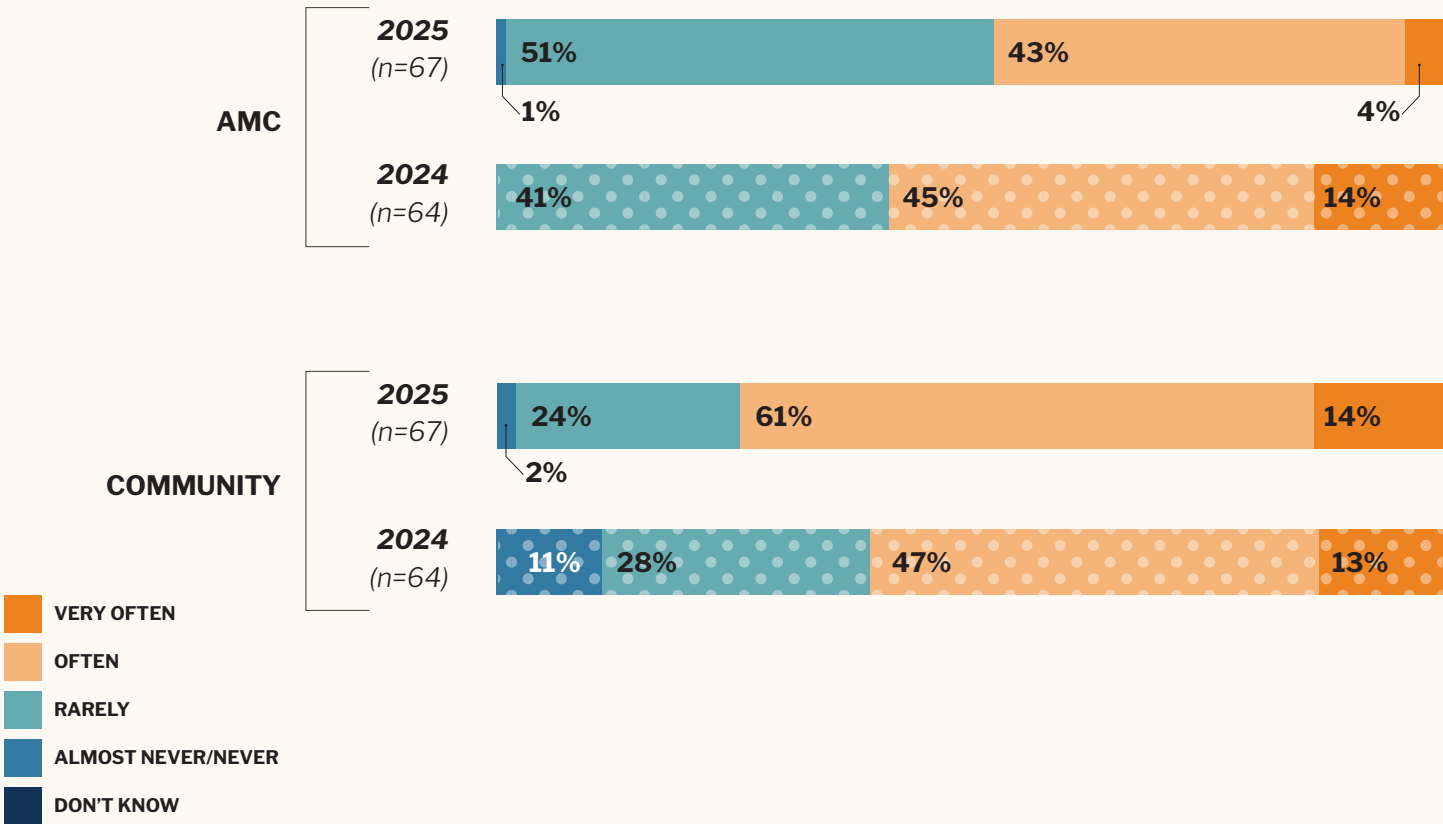
How much do you agree or disagree with the following statement:

The U.S. healthcare system is incompatible with high-cost CGTs.



Patients referred for CGTs often receive other treatments instead—especially when they are based in the community.

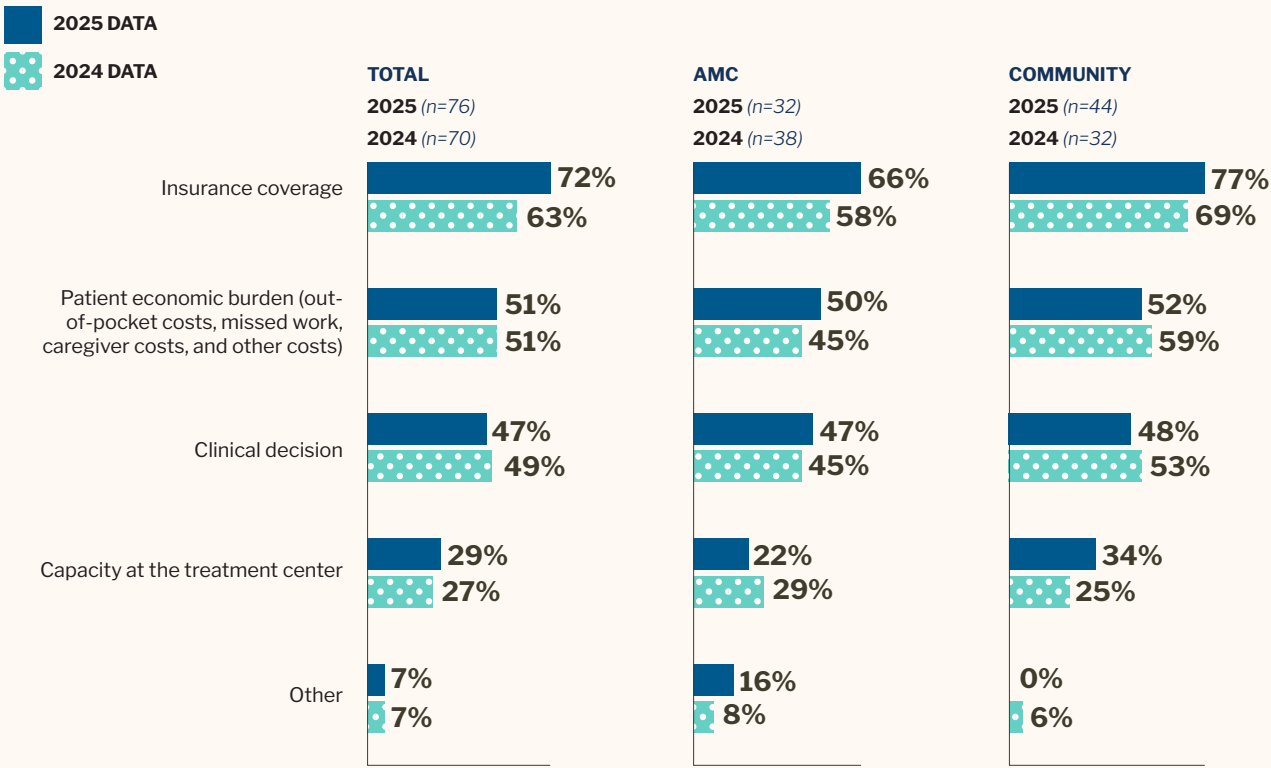
Based on your experience, how often are patients referred for a CGT but ultimately treated with another therapy?



Three-quarters (75%) of AMC oncologists say they have a CGT specialist (e.g. cell therapist) in their institution vs. only half (53%) of community oncologists.

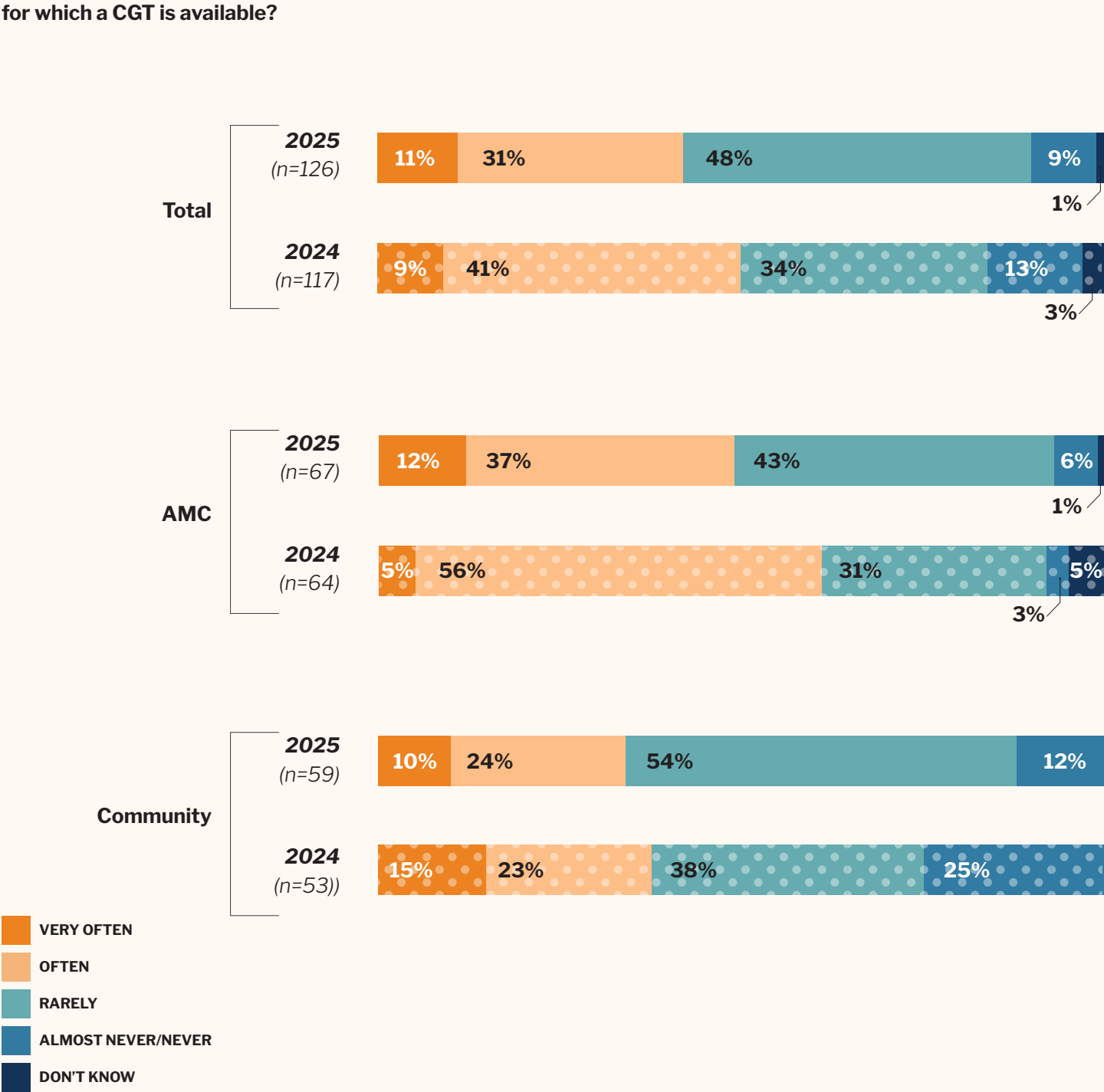
Insurance coverage and patient costs are the top reasons patients referred for CGT therapy don't ultimately receive it.

What are the most common reasons why patients who are referred for CGT don't ultimately receive it?



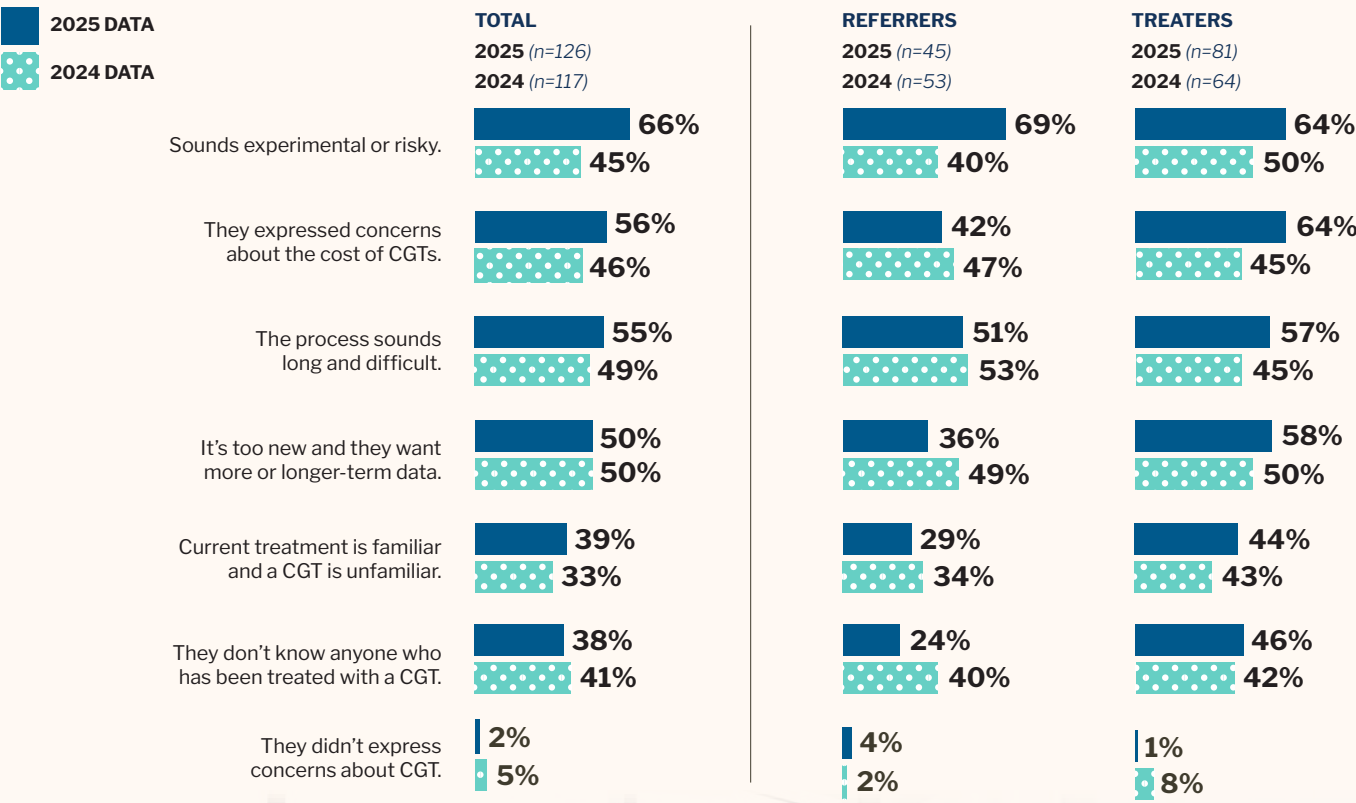
More than half of oncologists say patients rarely or never know about CGT available for their condition, an increase from last year.

How often are your patients aware of a CGT if they have a condition for which a CGT is available?



Concerns about CGTs being “experimental or risky” are common among patients, higher than last year.

When you refer/treat patients with CGTs/what are their most common concerns?



Expert perspective: MYLOVE MORTEL, MSPH, RN, OCN

Building the next wave: Inside UChicago’s plan to support the future expansion of CGT

When Mylove Mortel joined the team preparing for the clinical trial of what would become KYMRIA[®], the first FDA-approved CAR T therapy in 2017, she knew the field was on the cusp of something special. Mortel, Director of Transplant, Cellular Therapy and Advanced Hematology at University of Chicago Medicine (UChicago), said her organization started planning for what they believed would be growing demand for the new class of immunotherapies before they were available commercially.

“Even at that time, we knew it was going to change the space,” Mortel said. “We knew we needed to have a business arm to handle the growth of the program and the clinical research, because it was going to go hand in hand,” she said.

Eight years and more than a dozen FDA-approved CAR T therapies later, with hundreds more in clinical development, UChicago has met the expanding demands of drug sponsors and patients by organizing a centralized program that can quickly adapt to new products and protocols. Everything, from business planning to nurse education and clinical trial management, was designed to scale with the science.

“We broke it down into multiple components: clinical, educational, research, and business,” Mortel said. “We knew we needed institutional support, and bed access was made a priority from the beginning.”

Today, the institution’s approach means that any cell or gene therapy, whether commercial or investigational,

for oncology or emerging indications like autoimmune disease, is funneled through a single program. The result helps the organization stay ready for an influx of patients, she said.

Workforce Strain: A National Challenge, Felt Locally

As the number of CGTs has grown, so has the complexity of delivering them. In some cases, patients need to have their immune cells collected, a process called apheresis, then wait while the therapy is manufactured and shipped back. Hospitals need to manage the logistics of coordinating these visits, including beds, infusion schedules, and follow-up appointments—many of which cannot happen without enough skilled staff available to handle the work. Other CGTs require patients to get chemotherapy ahead of time to prime their immune system to accept the therapy.

As each therapy comes with specific instructions from manufacturers or varying guidelines from regulatory agencies, there is no standard way to educate the emerging workforce on administering and handling these medicines. According to a recent study, this is compounded by the broader shortage of workers across the field, and changes will need to occur in order to accommodate the growing number of therapies and patients who may want them.¹

“Multiple professional organizations in the CGT field agree that workforce development and standardization are essential in order to sustain and support the rapid growth in the CGT field,” the study authors wrote. However, with hiring lagging and a lack of attention to standardization, “this affects CGT

workforce positions at all levels, including technicians, technologists, laboratory managers, quality specialists and scientific and medical directors.”

“We’re recruiting for multiple positions right now,” Mortel said. “Ideally, we want individuals who have a true blood



disorder background because the acuity and the type of patients are just incredibly different from your solid tumor cancer patients.”

Technical Bottlenecks Remain

While UChicago’s investment in dedicated staff and infrastructure has kept bed access from becoming a bottleneck, other challenges remain.

“For me, it’s not beds, it’s not apheresis, it’s cell processing that has struggled to keep up,” Mortel said. “Due to the technical specialty expertise needed, recruitment and training takes time.”

Despite these hurdles, the push to expand access continues. The hospital’s outpatient unit, originally built with autologous transplants in mind, now handles most post-discharge follow-up and CAR T infusions, allowing the inpatient unit to focus on patients who need a higher level of monitoring or intervention.

Preparing for a Bigger Future

The pipeline for new cancer treatments is robust. According to the American Society of Cell and Gene Therapy, more than 2,100 gene therapies, including CAR T, are in active development worldwide.²

“We knew we needed to have a business arm to handle the growth of the program and the clinical research because it was going to go hand in hand.”

UChicago is already expanding to help process the expected demand, with a new 575,000-square-foot, \$815 million facility set to open in 2027 as the first freestanding cancer pavilion in Illinois.³ Its mission: to bring more than 200 cancer experts together and serve as the flagship for high-acuity, innovative cancer care on the South Side and beyond.

The new building will feature a 12-bay outpatient unit dedicated to CAR T, expanded inpatient capacity, and a focus on delivering the latest therapies as standard of care. It is also designed to serve the broader community, where cancer remains the second leading cause of death, with resources for screening, prevention, and health equity.³

Outpatient CGTs: The Next Frontier

The shift toward outpatient delivery of CGTs is already underway. Recent FDA changes have safety monitoring regulations and made it clear that management of key side effects is now standard clinical practice.⁴

“We know that the direction of the field is that more and more of these therapies are going to be outpatient,” Mortel said. “The focus has been, how do we also enable our network sites to deliver these therapies? Right now, everything is still funneled to the main campus, but the goal would be to slowly enable our network to offer run-of-the-mill CAR T products.”

Looking Ahead

As the field of CGT continues to grow, both in number and in the range of diseases they can treat, the challenges for hospitals will keep evolving. UChicago’s investments in people, infrastructure, and innovation offer one template for how to meet them. But for Mortel, success will depend not just on buildings or technology, but on building and retaining the next generation of experts.

“Back in the day, we didn’t know who all of these players are,” she said. “Now I know all my coders, my specialty billers, my managed care team, and supply chain folks that you wouldn’t normally interact with in any regular transplant program.”

Learning the ins and outs of every aspect of administering these complex therapies is highly specialized, and not something that’s easily learned through schooling or special programs—it often requires on-the-ground experience, she said.

“What worries me, not just for my organization but in general, is that a lot of us have been in the trenches together since the beginning, and unfortunately a lot of these folks are going to retire in the next five years,” Mylove said. “How do we replace those folks in these administrative positions who are holding the pieces together?” ●

We know that the direction of the field is that more and more of these therapies are going to be outpatient. The focus has been, how do we also enable our network sites to deliver these therapies?

— Mylove Mortel, MSPH, RN, OCN
Director of Transplant, Cellular Therapy and Advanced Hematology at University of Chicago Medicine

Expert perspective: IVAN BORRELLO, MD

Expanding cell and gene therapy access: a community hospital perspective

After 25 years at Johns Hopkins, Ivan Borrello, MD, joined Tampa General Hospital (TGH) in 2022 with a mission: build a program that could provide patients with the same cutting-edge cell therapies that are more readily available at large academic medical centers.

Borrello, a translational investigator in multiple myeloma, bone marrow transplant and cell therapies, had the right background to take on this project. He has been involved with cancer



immunology and immunotherapy since its infancy in the 1990s and is recognized as a leader in the field.

The challenges Borrello and TGH faced in this effort were multifaceted, from establishing treatment guidelines, bringing on staff with the right training and expertise, to building relationships with payers to enable coverage approvals. But the benefits—expanding patients to access to these therapies closer to home—greatly exceed the barriers.

“These people have to be in the hospital and their families need to take time off from work to take care of them. All of these things need to be factored in,” Borrello said.

Building from the Ground Up

At Johns Hopkins, infrastructure and processes for CGTs were long established, but TGH was starting at square one. That meant Borrello needed to build everything from scratch: creating procedures and guidelines, educating staff about basics like the urgency of treating neutropenic fevers, building an outpatient transplant unit, and developing the accompanying systems to deliver these therapies.

Borrello said he was fortunate to have the support of TGH’s CEO, who understood the long-term benefit, not just for oncology patients, but also in areas like rheumatology and neurology in the future. “It’s not just hiring a physician to build a BMT cell therapy program. You need a hospital-wide infrastructure to do this, and it requires a significant commitment,” Borrello said.

The process of building the internal expertise has taken time. Borrello has committed himself to teaching emergency room physicians and ICU staff about managing the serious side effects that can occur with CAR T-cell therapies.

“As we talk about expanding cell therapy into the community, this is something that cannot be underestimated,” he said. “There have to be standard operating procedures. People need



There have to be standard operating procedures. People need to understand that there needs to be adequate coverage at night and a hierarchy of who’s going to be contacted if symptoms escalate.

— Ivan Borrello, MD
Medical Director of the Myeloma, Bone Marrow Transplant (BMT) and Cell Therapies program, TGH Cancer Institute

to understand that there needs to be adequate coverage at night, and a hierarchy of who’s going to be contacted if symptoms escalate.”

That work has paid off. TGH is going through the process of FACT accreditation, an independent designation that would help sway insurers to sign off on more patients receiving cell therapies at the hospital.

“A lot of payers won’t approve cell therapies for us because we’re not a FACT-accredited institution,” he said. “I think it is going to give us a level of confirmation in the community to go forward.”

A Hybrid Model Emerges

TGH’s position as a community hospital has created what Borrello describes as a unique “hybrid model” that combines elements of both community and academic medical centers. While larger cancer centers are referring patients who have already been diagnosed, community hospitals like TGH may be the first stop for patients who are experiencing symptoms but have no diagnosis.

This hybrid approach has allowed TGH to be “innovative and also potentially quicker” in implementing changes, while building toward academic-level specialization with dedicated specialists for different cancers, he said.

These efforts include building a manufacturing facility to make cell therapies nearby. While requiring a significant financial investment, the capabilities will position TGH to expand access to these therapies as they are developed for conditions beyond cancer, such as autoimmune disease.

The Hub-and-Spoke Solution

Borrello sees a path forward to expanding CGTs into community settings through a “hub and spoke model,” where major centers develop best practices and guidelines for administering new therapies that they can share with smaller community hospitals and clinics, along with support and education.

Under this model, established centers like TGH would audit community hospitals using a checklist similar to FACT accreditation requirements, provide education through seminars, and maintain close oversight through daily rounds when patients are hospitalized.

“It’s going to be one of these things that sort of gradually expands out, but it needs to be done with close monitoring by the ‘mothership,’ until that level of expertise has been achieved in these smaller hospitals,” he said.

Education as Foundation

Central to making the hub-and-spoke model work is comprehensive education across multiple departments. When expanding into community settings, Borrello suggests knowledge sharing with other providers on topics as diverse as setting up financing systems, inpatient procedures, checklists for emergency rooms, and post-treatment monitoring standards.

The need for specialized expertise extends beyond clinical staff. When TGH first started offering CAR T, the staff didn’t have much experience routing CGTs through insurance companies for approval and were facing frequent roadblocks. Building relationships with the right people at payer organizations helped change things.

“Knowledge is power. You ask the right questions, you give the right information,” Borrello said. “You develop a relationship, and you develop credibility. It streamlines the process.”

Strict Standards, Careful Expansion

While Borrello strongly supports expanding access to cell and gene therapies, he said not every hospital can or should offer these treatments. Success requires deep institutional commitment, significant investment, and experienced leadership willing to maintain strict standards.

“I think the key thing is to have a framework, to have SOPs, and to have someone who has the power to say, ‘this is what we can do and this is what we can’t do’...no matter what the external pressures are.” ●

Payer Perspectives: A View on CGT Reimbursement

Examining the path to broader coverage approvals

As discussed throughout this report, expanding access to CGTs will require alignment across three core stakeholder groups: providers, biopharma manufacturers, and payers.

While much attention is often given to the clinical delivery and development of CGTs, the role of payers is equally critical. Without clear coverage pathways and reimbursement strategies—including innovative payment models—these therapies will be challenged to reach the patients who need them.

Yet payers are often perceived less as enablers, and more as barriers. In fact, surveyed oncologists cited insurance coverage as one of the top reasons why patients referred for CGT ultimately don’t receive it. This perception highlights a tension at the heart of the CGT ecosystem: balancing the extraordinary promise of these therapies with the financial and operational constraints of a complex and cost-sensitive healthcare system.

Payers Recognize the Importance of CGTs

The findings challenge several commonly held assumptions about payers in the CGT space. Contrary to the perception that payers are skeptical of innovation, 90% of those interviewed agreed that CGTs are among the most important medical advancements of our time, 80% believe CGTs are effective, and 90% consider them safe for clinical use. These responses suggest that most payers recognize the transformational potential of CGTs and are not inherently opposed to covering them.

However, there is a clear and persistent concern around the long-term durability of CGTs. In a theme consistent with our provider research, payers indicated that it is difficult to evaluate long-term value without data extending five years or more. While approximately one-third of approved CGTs have reported five-year follow-up data, many of the new therapies

Payers expressed a desire for greater visibility into the clinical rationale behind treatment decisions, greater clarity into where and how CGTs are being delivered, and better communication around patient outcomes. They also noted that inconsistent partnership with treatment centers makes it more difficult to assess and manage CGT performance at scale.

Payers Are Open to Innovative Payment Models—With Conditions

When asked about the role of innovative payment models, most payers expressed support for the concept, but operational realities tempered enthusiasm. Many payers stated that manufacturers are often unwilling to engage in meaningful negotiations, and when contracts are offered, they tend to be heavily skewed in favor of the manufacturer.

Several systemic barriers to the adoption of value-based payment models were also cited, including member portability, with payers expressing hesitation to invest in a one-time therapy if another payer may ultimately benefit from the outcomes. Similarly, the inability to collect outcomes data across siloed electronic health records (EHR) systems was identified as a major hurdle. Without the ability to retrieve the data to track patient progress over time, payers say it is difficult to assess whether these therapies are delivering on their promises.

To make innovative payment models viable, payers emphasized easy-to-measure, clinically relevant endpoints. There was broad agreement that when endpoints are subjective, slow to manifest, or inconsistently defined, it can erode confidence in contract performance and inhibit broader adoption.

Financial Risk Management Remains a Challenge

Like providers, payers are also grappling with the need to manage CGT-related financial risk in the short term. All commercial insurers reported using strict prior authorization protocols to ensure that only eligible patients receive therapy, such as basing coverage approvals on clinical trial eligibility requirements, which can often be more restrictive than FDA labeling. Many also rely on cost-spreading mechanisms, such as reinsurance or risk pooling, to manage the cost burden.



One area where payer perspectives were more divided was on the question of moving CGT into community care settings. Roughly half of the interviewed payers believe expanding CGT into the community is necessary to improve access and patient convenience. Others prefer to centralize care at academic or specialty centers, where they believe there is more consistency in clinical and financial outcomes. This split reflects ongoing tension between access and control.

Ultimately, the message from payers was clear: they recognize the value of CGTs and want to support broader adoption, but doing so will require greater transparency from treatment centers, more proactive and balanced negotiation from manufacturers, and new tools and processes for tracking patient outcomes over time. As the CGT pipeline continues to expand, the role of payers will become more critical, and so too will the need for deeper alignment across all stakeholder groups. ●



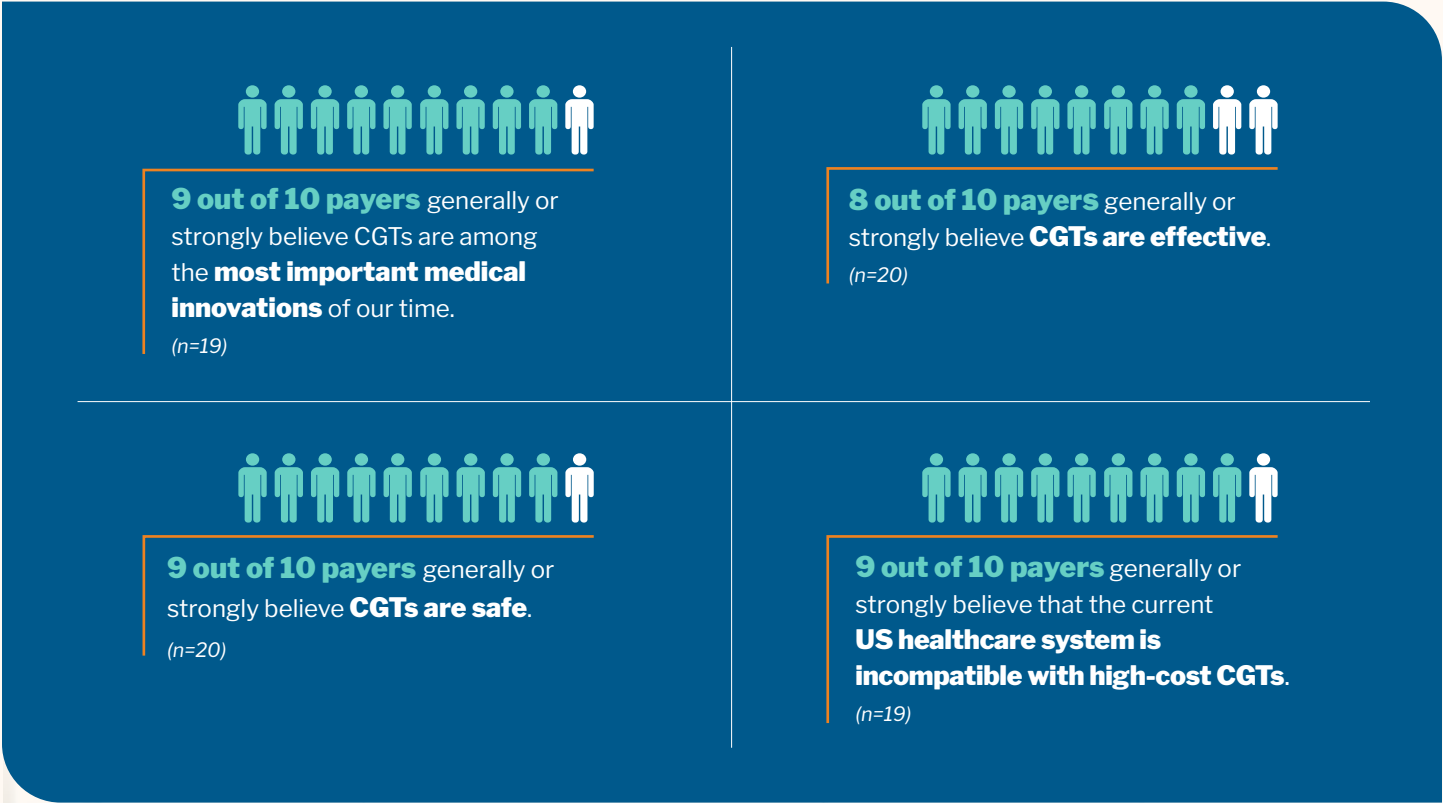
To make innovative payment models viable, payers emphasized easy-to-measure, clinically relevant endpoints.

To better understand how payers are navigating this tension, InspiroGene conducted interviews with 20 payers representing a diverse cross-section of organizations, including national and regional commercial health plans, Medicare and Medicaid managed care plans, and Integrated Delivery Networks (IDNs). The goal was to gain deeper insights into how payers perceive the landscape of CGT coverage, identify the primary friction points, and uncover opportunities for greater alignment.

have not yet.¹ This creates a challenging dynamic: payers are being asked to make high-stakes coverage decisions for high-cost therapies without long-term durability data.

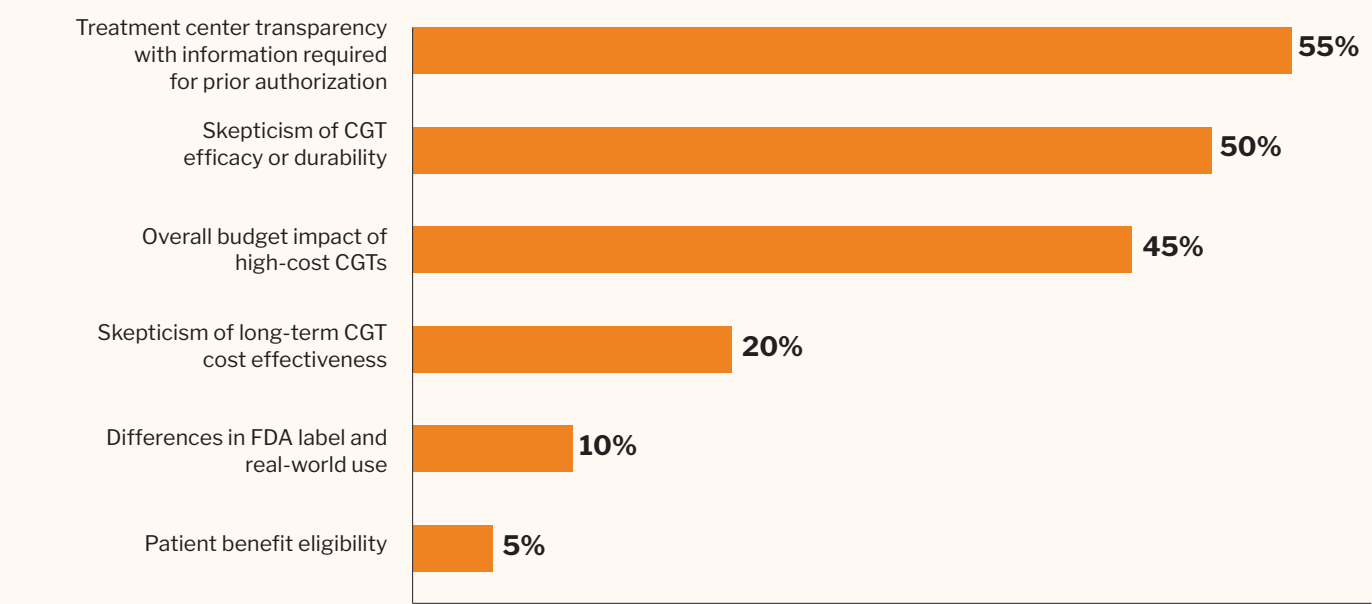
Surveyed payers also acknowledged that the U.S. healthcare system is not well-equipped to manage the high one-time costs of CGTs. Encouragingly, benefit eligibility was not often seen as a significant barrier to coverage. However, cost was cited as a major concern, and many participants pointed to broader operational issues—such as a lack of transparency from treatment centers and limited clinical documentation supporting the need for treatment—as key contributors to coverage barriers.

Payers overwhelmingly believe CGTs are safe and effective, but say they are not compatible with the U.S. healthcare system.



Patient benefit eligibility is not a primary barrier to coverage approval, say most payers.

What are the primary barriers you face when evaluating coverage decisions for CGTs? (choose all that apply) (n=20)

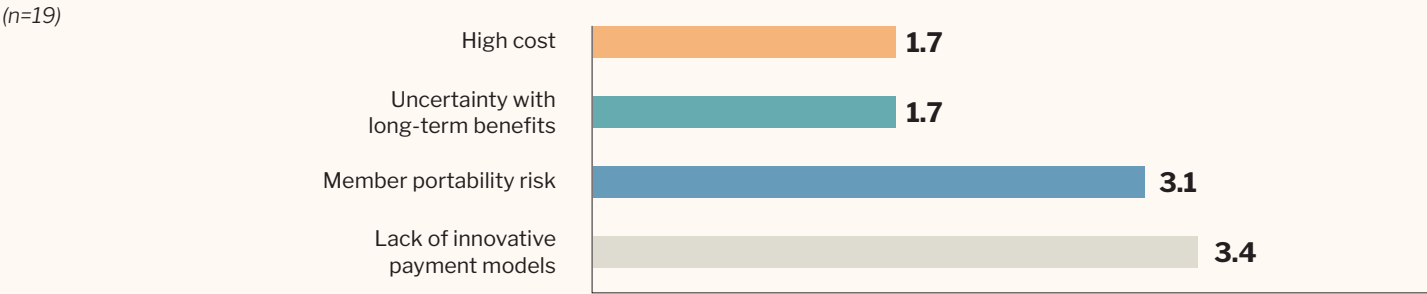


Payers strongly prefer treatment centers to procure CGTs through in-network specialty pharmacies (SPs) and expect SP use for CGTs to increase in the future.

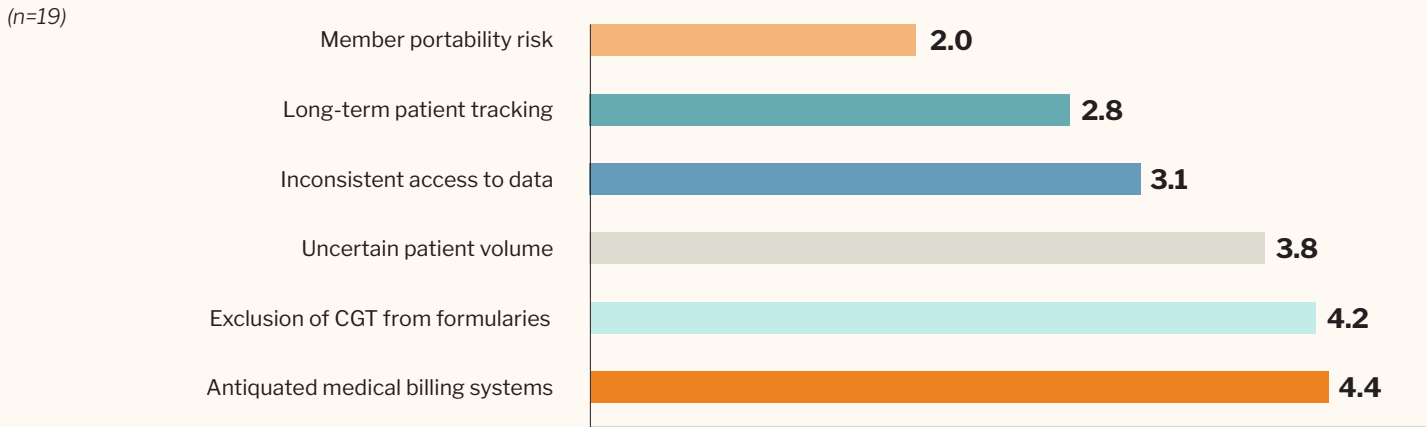
A photograph of a pharmacist in a white lab coat working behind a pharmacy counter, looking at a tablet device. Shelves of medicine are visible in the background.

Payers say cost and uncertain durability top the list of challenges to CGT reimbursement.

Please rank the following CGT-specific challenges when considering reimbursement on a scale from 1 to 4 where 1 = most significant and 4 = least significant.



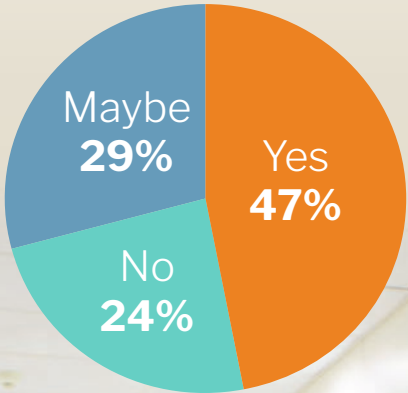
Which of the following factors are more likely to cause low adoption of innovative payment models among commercial payers? Please rank the barriers on a scale of 1-6 where 1 = most significant and 6 = least significant.



Nearly half of payers say expanding CGT into community sites is necessary.

Is expanding CGT into community hospitals and practices necessary to ensure broader access to patients?

(n=17)



“It’s a topic of conversation all the time in our organization: how we are going to manage the CGTs? Not only today but in the future as well, knowing the potential for significant budget impact.”

—Payer, Regional Health Plan

Expert perspective: JAMES REILLY

Commercializing cell and gene therapies: Four keys to success.

As the CGT field matures, new challenges are emerging on the path, from FDA approval to broad patient access. While exciting scientific breakthroughs continue to expand the pipeline, manufacturers seeking commercial success must navigate a complex landscape shaped by

Build a Strong Value Proposition

Foundational to a successful CGT launch is a clear and concise value proposition that describes how the new therapy is different from the current standard of care (SOC). Manufacturers must be able to clearly explain how their therapy improves on existing options and present data that speaks to each stakeholder.

A well-defined value proposition is especially important in areas where outcomes with SOC are already strong. In these cases, being able to demonstrate significant improvement, such as extended benefit, improved quality of life, or fewer side effects, may be needed to convince providers and payers to make a change.

“Communication strategy and execution is critical. Where I’ve seen manufacturers be more effective, they really have a clear value proposition that they can convey and they’re doing it consistently. So, you don’t have your commercial teams communicating one thing and your medical affairs and/or corporate communications teams communicating something else. Alignment is critical,” Reilly said.

Back Up Claims with Robust Durability Data

Long-term benefit is a priority for payers and providers. Evidence of a durable response is often required by payers to secure and retain reimbursement, especially for high-cost, one-time therapies. As part of the commercial planning process, biopharma manufacturers should consider what clinical trials and real-world evidence may be needed to support product uptake and drive favorable reimbursement, and they need to be ready to invest in gathering the necessary data.

Further, given that it can take time to establish long term durability in CGT, pre-launch engagement with payers is critical to align on what surrogate measures will be sufficient (e.g., disease progression, reduction in acute events, absence of retreatment) and tracked, and if outcome-based agreements will be needed. By partnering with payers in launch communications and planning, manufacturers can develop solutions that address payers’ durability questions and enable patient access.

“Will you have the data that’s going to show or help establish durability of response over time? That can be really powerful,” Reilly said. “If you don’t have that, it is important to proactively build your value rationale using interim clinical and natural history data to tell a compelling story.”

Engage Early with Payers, Providers and Patient Advocates

Early, sustained engagement with payers, providers, and patient advocacy organizations builds credibility and helps identify barriers ahead of launch. Reilly said involving these groups in advance supports faster adoption by prescribers and often leads to stronger payer support when it comes time to negotiate coverage.

“Those manufacturers that have done this well have gone out and they’ve been willing to stand behind the value of their products. They also had strong provider and KOL support along with patient advocacy. Early engagement with those stakeholders is critical,” he said.

Supporting patients with education, training, and administrative workflows is another way drugmakers help with uptake. Offering financial support, patient payment assistance where appropriate, and other logistical aid for travel will go a long way in ensuring a successful patient experience. Navigating coverage and reimbursement can be complex in the CGT world, so manufacturers need to ensure that patients have the necessary support.

“Making sure that there’s good investment in the support services is really going to matter,” he said.

Drugmakers also need to think through strategies for addressing potential logistical concerns that health systems and patients will face before approval so that the rollout isn’t hampered by these challenges.

“The last thing you want to have happen is the patient shows up there and then there’s a disruption and they can’t get the therapy that they need,” he said. “The distribution and treatment logistics, particularly for cell therapies, are complex and require a rigorous focus on quality, training, and execution.”

Understand the Financial Landscape

In disease areas with high unmet need, CGTs have delivered broader and faster adoption, especially when positioned and priced to reflect the needs and expectations of the treatment ecosystem. However, in disease areas where patients have available therapies that are delivering satisfactory outcomes, the calculations change.

Gene therapies for hemophilia, for example, faced significant pushback when high prices and uncertainty about long-term results met a population already well-served by reliable, lower-cost treatments.¹

Reilly also noted that successful commercialization depends on understanding the full range of financial levers at play beyond the list price, such as the impact of competitors contracting with providers and/or payers. Negotiations can determine whether a new therapy secures favorable coverage or is relegated to a higher-cost tier, regardless of its scientific merits.

Reilly emphasized that manufacturers should engage early with payers and providers while conducting market research to understand these dynamics and, where necessary, structure agreements that align incentives across the ecosystem.

“That can play a big role in some therapeutic areas,” he said. “Understanding this early and having a thoughtful mitigation strategy is critical.”

Strategic Alignment Drives Commercial Success

The CGT market is growing more complex. Broad adoption requires more than scientific progress—it calls for strong data, early engagement, and pricing strategies that reflect the realities of payers and providers. The most successful manufacturers listen to stakeholders, respond to feedback, and provide clear, credible evidence of value.

Unlike the early years where each new cell and gene therapy was a scientific breakthrough, a regulatory first, and often the only treatment for certain diseases, the market has become much more competitive. Success now hinges on strategic execution.

“Where I’ve seen challenges is when a manufacturer waits too long to figure out the strategy and what’s needed to support the therapy, and then it’s scrambling to try to address these needs by launch,” Reilly said. “It takes time, discipline, and expertise to understand the potential access issues along with the best near/long term mitigation strategies. Moving from strategy to precise execution when you have your pivotal data is critical—that’s a real inflection point where there is significant opportunity.” ●

“

Communication strategy and execution is critical. Where I’ve seen manufacturers be more effective, they really have a clear value proposition that they can convey and they’re doing it consistently too.

”

— James Reilly
Co-Founder and Managing Partner
of A3Access Advisors



payer expectations, provider skepticism, and heightened scrutiny on value.

James Reilly, Co-Founder and Managing Partner of A3Access Advisors and a veteran of market access strategy, said therapies that are scientifically sound and medically effective can still struggle commercially if the right prep work isn’t completed well in advance of approval. Reilly has deep experience in this space, both as a consultant and an in-house leader. He spent 25 years at Genentech during a time when the biotech giant launched a string of blockbuster medicines for cancer and other challenging diseases—including Rituxan, Herceptin, Avastin, and Perjeta—that would help define standards of care.

Based on his expertise and experience, Reilly offers four lessons for manufacturers striving to deliver on the promise of CGT.

On the map: Locations of qualified treatment centers (QTCs) for cell and gene therapy across the U.S.

Treatment site growth is flat from 2024 to 2025.

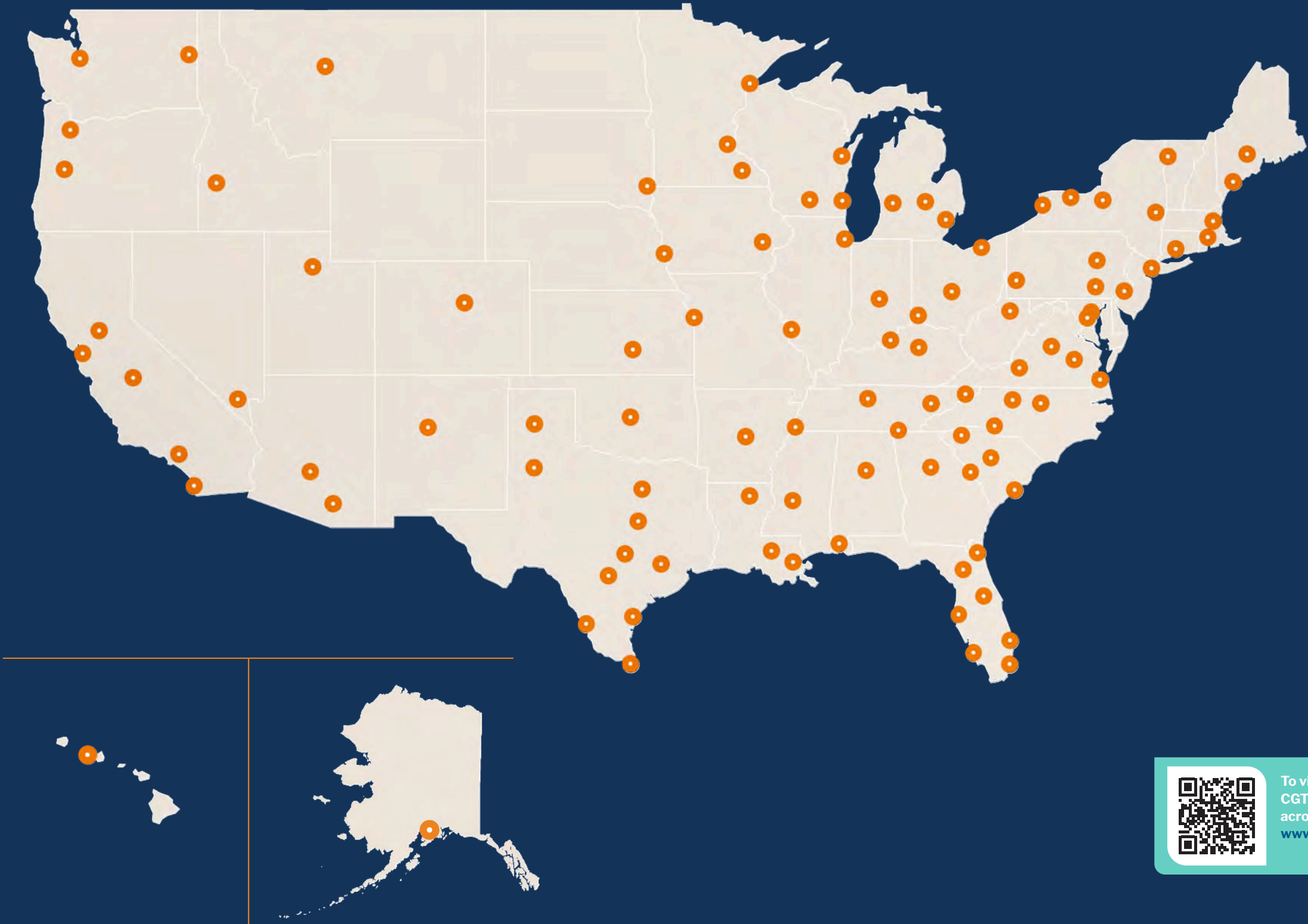
In 2024, InspiroGene created the first comprehensive map of qualified treatment centers (QTCs) for cell and gene therapy across the U.S., validating that most CGT care takes place in academic medical centers and major health systems in densely populated urban areas.

As discussions around the need to expand CGT care into community care settings continue, our 2025 research found that the total number of treatment sites is largely unchanged from 2024. Although about 20 institutions have been newly designated as CGT qualified treatment centers over the past year, an equal number have dropped from the list.

The map underscores a key paradox in this year’s report: While availability of CGTs is growing, the pace of community setting expansion is still disappointingly slow for many providers and patients who feel challenged to access care close to home.

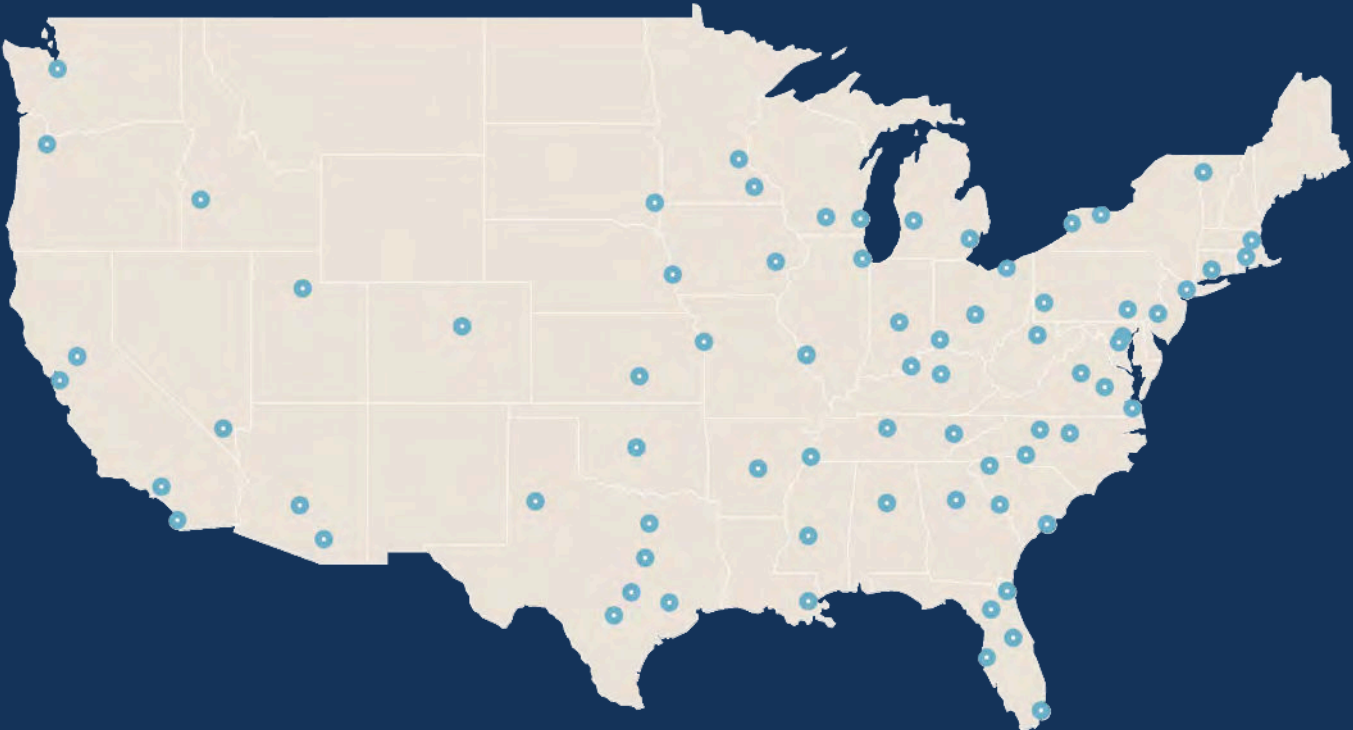
Explore the interactive map at www.inspirogene.com/qtcmap to dive deeper into the data.

Each dot represents a region or metropolitan area with one or more Qualified Treatment Centers (QTCs)



To view our interactive map of CGT qualified treatment centers across the U.S., visit www.inspirogene.com/qtcmap

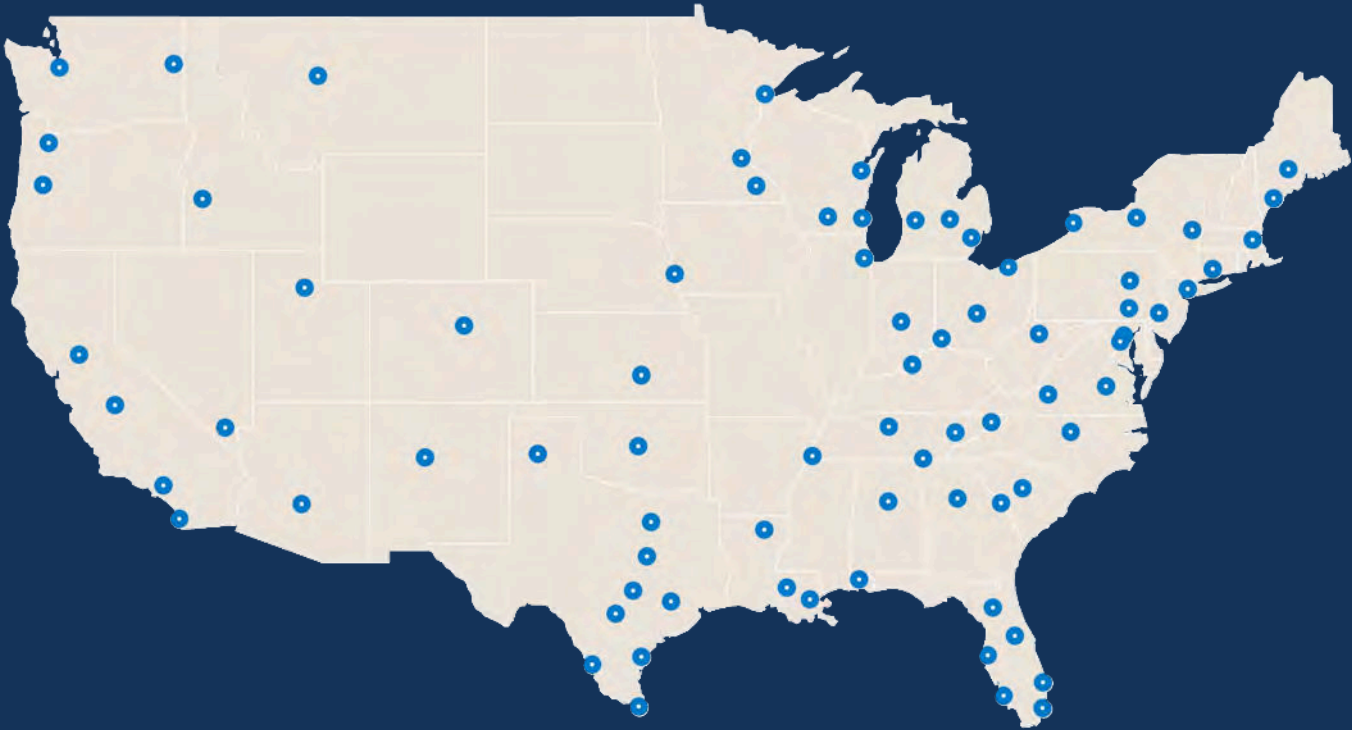
Cell therapy QTCs



- Regions with the most treatment centers:
- New York, NY** – 27 treatment centers
 - Los Angeles, CA** – 23 treatment centers
 - Philadelphia, PA** – 17 treatment centers
 - Boston, MA (Manchester, NH)** – 16 treatment centers
 - Chicago, IL** – 16 treatment centers
 - Dallas-Fort Worth, TX** – 10 treatment centers
 - Houston, TX** – 10 treatment centers
 - Tampa-St. Petersburg-Sarasota, FL** – 10 treatment centers

Gene therapy QTCs

Each dot represents a region or metropolitan area with one or more Qualified Treatment Centers (QTCs)



To view our interactive map of CGT qualified treatment centers across the U.S., visit www.inspirogene.com/qtcmap

Views from Top Industry Experts

Perspectives on the changes needed to drive wider CGT access for patients

This year’s CGT report highlights the continued progress the industry is making in developing breakthrough therapies and bringing them to market—but it also illuminates the ongoing challenges that are preventing the potential of CGT from being fully realized.

To understand what actions are most needed right now, we asked seven industry experts: **What is the single biggest obstacle that slows patient access to CGTs and what needs to be done to remove that barrier?**



Gary Simmons, DO, MSHA
*Oncologist/Cell Therapist,
Virginia Oncology Associates*

The biggest obstacle slowing the expansion of CGTs is gaps in current Centers for Medicare & Medicaid Services (CMS) models, which require community providers to manage significant financial challenges when adopting cell and gene therapies.

At Virginia Oncology Associates, we have successfully engaged commercial payers to align drug acquisition costs and reimbursement. However, 36 of our last 40 CAR T-cell therapy patients were covered by Medicare. Under current models, we incur losses in the tens of thousands per patient, before accounting for overhead costs. This strain is further complicated by lengthy reimbursement timelines that may leave millions of dollars in accounts receivable tied up for months, placing significant pressure on already limited operating budgets.

Despite these challenges, I am encouraged by the progress we have seen. Manufacturer rebates are helping address these gaps, and commercial payers are showing greater openness to support CGT delivery in the community setting. These shifts reflect a growing recognition of the critical role community practices play in expanding access. Sustaining this momentum, particularly through continued collaboration with policymakers and payers, represents a real opportunity to make CGTs more accessible in community sites of care. ●



Rocky Billups
*Vice President of Operations
HCA Healthcare/Sarah Cannon Cancer Network*

While there are several barriers slowing patient access to cell and gene therapies, I’d like to focus on the cost of the products and the role of specialty pharmacies in managing those costs. The high price tag associated with CGTs can have a significant impact on facilities, delaying their onboarding of this therapy. If pharma manufacturers want to accelerate the use of CGTs, they need to agree to offer specialty pharmacy as an option for securing the products.

Hospitals and community medical oncology practices cannot afford to have large amounts of product expense on their books while waiting for payer reimbursement. Reimbursement can sometimes take several months to be approved and may be underpaid. Providers also need robust revenue cycle management teams in place to manage pre-authorization and follow the product payment to ensure they are paid appropriately and in a timely manner. As the number of approved CGTs and new indications continues to grow, specialty pharmacies can play a critical role in decreasing these financial barriers.

Specialty pharmacies can also help community hospitals and medical oncology practices manage the logistics associated with cold chain and time-sensitive delivery of the product, and help ensure proper handling, storage, and transportation.

The product is the most expensive part of CGT; having a specialty pharmacy option removes risk to community oncology practices and to hospitals. This option is already working well for several approved CGTs and could accelerate the utilization of others in the future. ●



Elias Pittos, PharmD, BCOP, CSP
*Medical Director of Cell, Gene, and Advanced
Therapies, InspiroGene by McKesson*

Despite their transformative potential, CGTs face major access challenges due to high costs and complex financing. With list prices into the millions and U.S. spending projected to reach \$48 billion by 2030,¹ affordability remains the biggest barrier. Rising cost concerns have made it clear that access will largely depend on how payers manage the financial risk.

Unlike traditional therapies, CGTs are typically one-time interventions with front-loaded costs and uncertain long-term outcomes. As a result, payers face several risks: high initial cost exposure, member portability, unclear treatment durability, and follow-up of long-term outcomes.

In response to these risks, innovative payment models are evolving to improve affordability and predictability. Examples include amortization, which spreads payments over time; risk pooling, which distributes cost across populations; and performance-based agreements, which link reimbursement to outcomes.

With growing evidence of long-term clinical success, attention is increasingly shifting toward how financial risks can be addressed in ways that support access and sustainability. While each model offers value, no single solution is universally effective. What’s becoming clear is that solutions may involve a combination of strategies that align a payer’s risk profile with financial predictability and value realization. Ultimately, implementing these models at scale requires cooperation across the ecosystem. Payers, manufacturers, and providers each bring unique perspectives, and aligning around shared goals is key to turning innovation into real-world solutions. ●

Views from Top Industry Experts

What is the single biggest obstacle that slows patient access to CGTs and what needs to be done to remove that barrier?



Zahra Mahmoudjafari, PharmD, MBA, BCOP, FHOPA
Clinical Pharmacy Manager, Division of Hematological Malignancies and Cellular Therapeutics, The University of Kansas Health System

A major challenge and opportunity for the CGT field lies in strengthening coordination between academic centers and referring physicians. The FDA's recent decision to lift the REMS program for CAR T-cell therapies has underscored just how critical these handoffs can be in practice. To ensure continuity of care, authorized treatment centers must work closely with referring physicians by offering practical guidance and rapid-response communication channels.

Previously, patients were required to stay near treatment centers for four weeks of post-treatment monitoring and refrain from driving for eight weeks. Now, patients may return home and drive after two weeks. While this reduces a major logistical challenge for patients and caregivers, it also shifts responsibility for monitoring in weeks two through four post-treatment—when serious immune-related complications can still arise—onto referring providers.

Referring physicians are well-equipped to deliver excellent patient care, but the typical protocols from qualified treatment centers, with frequent visits and intensive lab testing, may not translate seamlessly into community practices. For a successful transition, academic centers must actively support their referring partners with clear, practical protocols and direct communication channels, potentially even through dedicated hotlines for rapid consultation.

As the field evolves, both authorized treatment centers and referring providers will become more comfortable and experienced in CGT follow-up care. In this transition period, however, close collaboration is crucial to safeguard patients and fully realize the benefits of these regulatory changes introduced to expand access. ●



Robb Richards, MBA, MS
Corporate Director, Cell Therapy and Transplant University of Pennsylvania

I think of the CGT space as three foundational pillars: clinical, financial, and operational. Clinically, physicians have always led the way. However, while physicians can understand the clinical value of these treatments, the business and operations sides are slowing adoption down due to the risk associated with delivering the care. Additionally, the “buy and bill” drug model is facing headwinds and driving payers to consider different payment models to cover CGT costs. Lastly, the pharmaceutical companies don’t understand the risk levels that an AMC or community practice assumes when delivering this care.

AMCs typically add more layers of management to mitigate the risk of delivering CGT care. Those layers ultimately add more cost to an already costly delivery system, and that bill goes to the payers. If you are a community-based hospital or practice, the cost of these therapies could significantly affect cash flow for what is typically a resource-challenged organization, lessening their desire to treat with CGTs.

If we hope to improve access to these treatments, payers must adopt easier (and faster) payment models that recognize what it truly takes to treat CGT patients, including runways for developing programs closer to home. It will also require aspiring treatment centers to develop comprehensive plans for delivering CGT care that can give payers confidence about covering care with very expensive treatments. Most importantly, it will require a willingness to embrace alternate payment models that are not “buy and bill.” ●



Timothy Hunt
Chief Executive Officer, Alliance for Regenerative Medicine

To be the global leader in cell and gene therapy, we need to continue to modernize aspects of the U.S. healthcare system, which is antiquated and designed for small-molecule drugs and chronic care. Realizing the potential of these next-generation therapies will require fundamental changes. We need nimble regulation and policy that responds to the pioneering and fast-evolving nature of CGTs to expand access for more patients.

The FDA's recent decision to eliminate REMS and update other labeling requirements for approved CAR T therapies is a monumental step forward. Previously, patients were required to stay near their treatment center for 28 days following dosing and were prohibited from driving for 60 days—potentially prohibitive barriers for many Americans. Reducing both requirements to 14 days will support broader accessibility for patients and a faster return to normal life. The changes were based on emerging real-world evidence that serious adverse events from CAR T treatments almost always occurred within the first 14 days of dosing.

Another positive step has been the launch of the Center for Medicare and Medicaid Innovation (CMMI) CGT Access Model, which allows CMS to negotiate outcomes-based arrangements on behalf of states, relieving them from having to negotiate their own terms. This voluntary pilot program for sickle cell disease (SCD) gene therapies exceeded expectations, with 33 states and two territories participating, representing 84% of Medicaid beneficiaries with SCD.¹

While these events are encouraging, more modernization is needed to broaden access. For example, since millions of Medicaid patients live in states without qualified treatment centers, a standardized provider credentialing and enrollment process across states would eliminate unnecessary delays for patients seeking care out of state.

Systemic modernization is essential to fulfill the promise of CGTs. Regulatory and policy decisions based on real-world evidence are already making a difference for patients and must continue to eliminate unnecessary barriers to access. ●



Joseph Mikhael, MD, MEd, FRCPC, FACP, FASCO
Chief Medical Officer, International Myeloma Foundation, Professor, Translational Genomics Research Institute (TGen), an affiliate of City of Hope Cancer Center

In my experience as a treating clinician and patient advocate, one of the most important steps to increasing access to CGTs is empowering and educating patients with the resources that will enable them to have informed conversations with their physician about their disease and their treatment options.

Physicians bring their own expertise, experiences, and perspectives to the treatment discussion. But sometimes, they may prematurely assume patients are unable to travel for CGT treatment, or think they don’t have the necessary caregiver support, which could dissuade them from even starting the CGT conversation with eligible patients. When patients enter the clinic asking informed questions, physicians and patients can participate in the shared decision-making process, where treatment options are evaluated based on several criteria, including patient preferences.

To successfully educate and empower patients, we need to reach them where they are. Patient advocacy groups and other stakeholders across the CGT ecosystem must take a multi-modal approach to provide accurate, vetted information in both in-person and virtual settings, including social media, apps, and AI chatbots.

Ensuring that community providers are prepared for these discussions is also critical—and this is where academic medical centers can play a key role. In the case of myeloma, closer collaboration is needed between community oncologists, who treat the majority of patients, and myeloma specialists, who are concentrated in these centers of excellence. When specialists are more accessible to these providers, they can help strengthen the foundational knowledge of CGTs and support more productive conversations with patients.

Patient education and empowerment is a win-win: it educates and empowers the patient, it equips the community oncologist, and it facilitates the work of the specialist. ●

Expert contributors



Joe DePinto
*Head of Cell, Gene, and
Advanced Therapies,
InspiroGene by McKesson*

Joe DePinto has spent the past 30+ years focused on bringing life-saving specialty drugs to market, helping patients with complex diseases to access advanced care and helping to develop future leaders in the pharmaceutical industry. As Head of Cell, Gene, and Advanced Therapies at McKesson, he has responsibilities over working with teams and customers to find new and better solutions to today’s cell and gene value chain challenges while looking toward the development and identification of strategies that can help meet tomorrow’s opportunities. Joe’s past roles have included leadership positions at top pharmaceutical companies including Johnson & Johnson, Lilly, Sunesis, and Dendreon. His core leadership competencies include driving all aspects of strategy, drug development, investor relations, and commercialization with multiple global launches. DePinto holds a Bachelor’s in Marketing and an MBA with an emphasis in Pharmaceutical/Chemical Studies.



Navneet Majhail, MD, MS, FASTCT
*Physician-in-Chief of
Blood Cancers
Director, Sarah Cannon
Cancer Network*

Dr. Navneet Majhail is the Physician-in-Chief of Blood Cancers at the Sarah Cannon Cancer Network, the cancer service line of HCA Healthcare. He oversees the Sarah Cannon Transplant and Cellular Therapy Network, which includes 10 programs providing care to 1,500+ transplant and cellular therapy recipients annually. Dr. Majhail has served as faculty at the University of Minnesota and the Cleveland Clinic, and held leadership roles at the National Marrow Donor Program and the Center for International Blood and Marrow Transplant Research. He was President of the American Society for Transplantation and Cellular Therapy in 2019 and Chair of HRSA’s Advisory Council on Blood Stem Cell Transplantation (2022–2024). He is currently Vice President of the Foundation for the Accreditation of Cellular Therapy and serves on the NMDP Board of Directors. His research focuses on transplant outcomes, health services, policy, quality of life, and late effects in transplant survivors.



Mylove Mortel, MSPH, RN, OCN
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Mylove Mortel is Director of Transplant, Cellular Therapy and Advanced Hematology at the Jonas Center for Cellular Therapy at University of Chicago Medicine (UChicago). At UChicago, she is actively involved in strategic planning, development, and implementation of the Cellular Therapy program to deliver commercial and investigational therapies (including CARs, TILs, and TCRs) for heme and solid tumor malignancies. She is also leading the effort to establish the Transplant and Cellular Therapy Program as the centralized program of record for all cellular and gene therapy-based clinical trials at UChicago. Mortel received her MSc in Public Health and BSN from the University of Illinois at Chicago. She is an experienced clinical and administrative operations director with expertise in stem cell transplant, CAR T-cell therapies, clinical research, FACT accreditation, and quality management. She is Past Chair of the ASTCT Administrative Director SIG Steering Committee and served as a faculty speaker for its leadership course.



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*Medical Director,
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Dr. Ivan M. Borrello is a hematologist-oncologist and physician-scientist who serves as the Medical Director of the Myeloma, Bone Marrow Transplant, and Cell Therapies program within the Tampa General Hospital Cancer Institute. He is recognized as a leader in the field of immunotherapy for hematologic malignancies, as well as bone marrow and stem cell transplants. Dr. Borrello was previously with the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, where he was Medical Director of the Cell Therapy Lab, a member of the Cancer Immunology and Immunotherapy Program, the Cellular and Molecular Medicine Graduate Program, and an Associate Professor of Oncology. He received his MD from the Medical College of Virginia, completed his Internal Medicine residency at the University of Chicago, and fellowship in Medical Oncology at Johns Hopkins. Dr. Borrello’s research focuses on immune-based therapies for multiple myeloma and other diseases. He has published 100+ peer-reviewed articles and holds numerous inventions, patents, and copyrights.



James Reilly
*Co-Founder and
Managing Partner
A3Access Advisors*

James Reilly brings more than 30 years of diverse commercial leadership experience in biotechnology and healthcare. During this time, he has held multiple executive internal and field-based leadership positions across market access and sales while at Genentech for 25 years. His responsibilities have spanned the full spectrum of market access and commercial strategy, including account management, distribution, pricing, contracting, and operations. He has significant experience in developing and executing innovative distribution and access strategies and has been involved in the successful launch of over 30 new medicines and hundreds of new indications across many therapeutic areas including Oncology, Neuroscience, Autoimmune Diseases, Hematology, Rare Diseases, and Ophthalmology. Reilly has also served as both a board member and Chairman for the HDA Research Foundation. Prior to Genentech, he led strategy and contracting efforts for a 600-member multi-specialty medical group. Reilly holds a BS in Health Science with a concentration in Healthcare Management from San Jose State University.



Gary Simmons, DO, MSHA
*Oncologist/Cell Therapist,
Virginia Oncology
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Dr. Gary L. Simmons is an oncologist at Virginia Oncology Associates in Norfolk. Dr. Simmons received his medical degree from the University of New England College of Osteopathic Medicine in Biddeford, ME, and completed his residency in Internal Medicine and subspecialty training in Hematology/Oncology at Virginia Commonwealth University in Richmond, VA. He is board-certified in internal medicine, hematology, and oncology. Dr. Simmons is recognized for his leadership in the development of several CAR T-cell programs in Virginia. In addition to performing numerous CAR T-cell procedures, he is also active in cell therapy research, frequently publishes papers, and gives local, regional, and national talks. He co-authored the BMTinfonet CAR T-cell handbook for patients in 2022. He has an extensive publication record of abstracts and papers and has presented his work at the American Society of Transplant Cellular Therapy and the American Society of Hematology. He currently serves as the Medical Director of McKesson Cell and Gene Therapy, as well as on the board of FACT Consulting.



Rocky Billups
*Vice President of
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Healthcare/Sarah
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Rocky Billups has been with HCA Healthcare for 28 years and joined HCA Healthcare/Sarah Cannon Cancer Network (SCCN) in 2011. He has more than 30 years of experience in hospital operations, clinical practice and developing oncology programs. Billups is responsible for the development and implementation of SCCN’s strategy for the delivery of a comprehensive and integrated blood cancer service line in the United States. He was instrumental in the development of the Sarah Cannon Transplant and Cellular Therapy Network in 2011 and facilitated the opening of Sarah Cannon Research Institute – UK, the first phase I oncology research facility in the private sector and accredited by the Care Quality Commission. Billups received his diploma in nursing from St. Mary’s School of Nursing in Huntington, WA and his Bachelor’s and Master’s degrees in Health Services Administration from Regis University in Denver, CO. He is a member of the American Society of Clinical Oncology, the American Society of Hematology, the American Society of Blood and Marrow Transplantation, and the Association of Community Cancer Centers.



Elias Pittos, PharmD, BCOP, CSP
*Medical Director of Cell,
Gene, and Advanced
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Elias Pittos earned his pharmacy degree from the University of Illinois at Chicago and is a Board-Certified Oncology Pharmacist (BCOP) with over a decade of experience in pharmacy benefit management and specialty pharmacy. Throughout his career, he has focused extensively on expanding access to cell and gene therapies (CGT), leading the development of formulary and specialty pharmacy strategies, pioneering innovative financial solutions, and refining medical drug management for high-cost therapies. He has played a key role in designing data-driven coverage models tailored to emerging CGTs, ensuring both clinical and financial sustainability. In his current role as Medical Director at InspiroGene by McKesson, Pittos works closely with manufacturers and healthcare providers to optimize the CGT value chain—enhancing accessibility, scalability, and affordability. He also chairs a clinical advisory council of CGT providers, addressing real-world challenges in treatment access and reimbursement.

Continued on following page

Expert contributors *continued*



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Dr. Zahra Mahmoudjafari is a board-certified oncology pharmacist and Clinical Pharmacy Manager in the Division of Hematologic Malignancies and Cellular Therapeutics at The University of Kansas Health System. Dr. Mahmoudjafari completed her pharmacy training at the University of Missouri-Kansas City (UMKC) and her PGY1 Pharmacy Practice Residency at The Ohio State University Medical Center in Columbus. She completed her PGY2 Oncology Residency at the Huntsman Cancer Institute in Salt Lake City, UT, and received her MBA from Henry W. Bloch School of Management affiliated with UMKC. Dr. Mahmoudjafari has presented nationally on numerous topics. She currently serves as the Secretary of the Hematology/Oncology Pharmacy Association (HOPA). In 2022, she was the recipient of the ASTCT Pharmacy Special Interest Group Lifetime Achievement Award and received ASCO's 40 Under 40 in Cancer Award. Dr. Mahmoudjafari is also Editor-in-Chief of Pharmacy Practice in Focus: Oncology and serves as a reviewer for several journal.

Robb Richards has over 20 years of experience in oncology, first with a private practice in Southern New Jersey and more recently the University of Pennsylvania Health System. He has served in different roles throughout his healthcare career: IT Manager for the Center for Cancer and Hematologic Disease in Cherry Hill, Division Chief Operating Officer of Regional Cancer Care Associates (RCCA) in Cherry Hill, New Jersey, and RCCA corporate VP and Chief Information Officer. He unofficially joined Penn's Cell Therapy and Transplant program (CTT) in 2016 and was the lead in overseeing operationalizing and implementation of CAR T-cell therapy for commercial use. He is currently the Corporate Director of The Center for Cell Therapy and Transplant program at Penn Medicine, with oversight of both commercial and research work and its expansion into community hospitals within the Penn system. Richards received his BS in Information Technology from Drexel University and both his MS in Informatics and MBA from St. Joseph's University.

Tim Hunt joined Alliance for Regenerative Medicine (ARM) as CEO in 2022 with more than 20 years of experience in the biotechnology industry. A company-builder with a focus on corporate culture, he has helped early-stage organizations create internal cohesion and advance strategic initiatives. As chief executive, Hunt divides his time between managing ARM and its global staff of nearly 30 employees and serving as an external advocate on behalf of ARM's membership and the broader cell and gene therapy sector. Hunt received a BA in history and philosophy from Boston College and a JD from the Columbus School of Law at the Catholic University of America.

Dr. Joseph Mikhael is a Professor at the Translational Genomics Research Institute, an affiliate of City of Hope Cancer Center. He is also the Chief Medical Officer of the International Myeloma Foundation. Dr. Mikhael is a consultant hematologist and Director of Myeloma Research at the HonorHealth Research Institute, where he conducts phase I clinical trials. He recently completed a term as Councilor on the American Society of Hematology Executive Committee and led the ASCO guidelines for multiple myeloma. Dr. Mikhael was formerly a hematologist at Mayo Clinic Arizona, serving as Professor at the Mayo College of Medicine, Associate Dean of Graduate Medical Education, and Deputy Director – Education of the Mayo Clinic Cancer Center. He has been recognized with numerous awards in education, including induction into the Mayo Clinic Resident and Fellow Association Hall of Fame as Educator of the Year. He was also named among the Top 100 Doctors in the United States. Dr. Mikhael trained in Ottawa and Toronto, completing a Hematology Residency and Multiple Myeloma Fellowship at Princess Margaret Hospital, along with a master's degree in Education from the University of Toronto.

Methodology

Provider Research Methodology:

McKesson worked with a third-party market research firm to conduct a double-blind 20-minute online survey of 126 U.S. oncologists between June 12 and July 7, 2025. All participants were board certified, had been in practice between 2 and 40 years, and had experience either treating patients with cell and gene therapies (CGTs) or referring patients for CGTs. Respondents represented a range of geographies, years in practice, and practice sizes.

Among the 126 oncologists, 64% were classified as treaters, with experience treating patients directly with CGTs or both treating and referring, and 36% were classified as referrers. Participants practiced in a variety of settings: 53% were based in academic medical centers and 47% were in community practices. Within the community group, 18% were at community hospitals and 29% were at community clinics.

Payer Research Methodology:

McKesson worked with a third-party research firm to conduct 20 double blinded in-depth qualitative and quantitative interviews with payer experts involved in U.S. cell and gene therapy (CGT) coverage. Eligible participants were individual decision-makers from national, regional, and Medicaid or Medicare managed care plans, as well as IDNs. Approximately 70% were Pharmacy or Medical Directors; other roles included Executive Director, VP of Pharmacy, and CMO. Roughly 80% of participants represented commercial health plans, and 50% came from organizations covering more than 15 million lives. Interviews were conducted virtually for 60 minutes and occurred in February and March 2025.

QTC Map Methodology:

McKesson partnered with a third-party data analytics firm to compile the data for the Qualified Treatment Centers map. Data was sourced in May 2025. Sources included the American Society of Gene and Cell Therapy (ASGCT), the Foundation for the Accreditation of Cellular Therapy (FACT), BMT Infonet, and product websites of numerous cell and gene therapies.

The database of the qualified treatment centers was organized by address and ZIP code, and then segmented using Designated Market Area (DMA) data, which defines distinct markets across the U.S. using ZIP codes.

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Introduction

Joe DePinto: Turning momentum into movement: Cell and gene therapy at a turning point

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