



Expanding Access to CAR-T Therapy Operational Models and Best Practices Across the Oncology Care Continuum

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Executive Summary

The delivery of chimeric antigen receptor T-cell (CAR-T) therapy is rapidly evolving as oncology practices seek to expand access beyond traditional inpatient academic medical centers. While advances in cellular therapy have transformed outcomes for patients with relapsed or refractory hematologic malignancies, implementing CAR-T therapy across diverse practice settings presents significant operational, logistical, and coordination challenges.

To better understand how organizations are addressing these challenges, NCODA conducted qualitative interviews with physicians, advanced practice providers (APPs), pharmacists, nurse coordinators, administrators, and operational leaders representing academic medical centers, community oncology practices, outpatient CAR-T programs, and rural referral networks. The goal was to identify practical approaches that support safe, efficient, and patient-centered CAR-T delivery across the oncology care continuum.

This white paper examines four predefined CAR-T practice archetypes representing distinct models of care delivery: formal referral partnerships, informal or emerging referral networks, fully outpatient CAR-T programs, and rural or geographically isolated referral models. Although these practice environments differ considerably in resources, infrastructure, and patient populations, the interviews revealed several consistent operational themes.

Across every archetype, participants emphasized that the greatest barriers to CAR-T therapy are increasingly operational rather than clinical. Insurance authorization delays, caregiver availability, travel and lodging requirements, communication between institutions, staffing limitations, and outpatient capacity frequently influenced patient access more than questions of clinical eligibility or toxicity management. These challenges were observed across both academic and community settings, highlighting that expanding CAR-T access depends as much on operational readiness as clinical expertise.

Successful programs shared several common characteristics regardless of practice setting. Strong multidisciplinary collaboration, clearly defined referral pathways, proactive patient and caregiver education, embedded pharmacy and APP support, and continuous communication between referring and treating teams consistently emerged as critical components of high-performing CAR-T programs. Organizations with mature operational workflows were better able to coordinate care, maintain continuity throughout the treatment journey, and adapt to the growing demand for outpatient and community-based CAR-T delivery.

While each archetype demonstrated unique strengths and challenges, the interviews also showed that many successful operational strategies are transferable across practice settings. Mature referral partnerships offer lessons for emerging networks, outpatient programs demonstrate how robust monitoring systems can safely reduce reliance on inpatient care, and rural practices illustrate innovative approaches to maintaining continuity despite geographic barriers. Collectively, these experiences reinforce that there is no single model for CAR-T delivery; rather, successful implementation depends on adapting proven operational principles to the needs and capabilities of individual practices.

As CAR-T therapy continues to expand into earlier lines of treatment and broader practice settings, scalable models of multidisciplinary coordination, shared care, and operational excellence will become increasingly important. By synthesizing real-world experiences from diverse oncology programs, this white paper provides practical insights that can help organizations strengthen referral pathways, improve care coordination, expand access, and ultimately ensure that more patients can benefit from these transformative therapies.

Introduction

Chimeric antigen receptor T-cell (CAR-T) therapy has fundamentally transformed the treatment landscape for hematologic malignancies, offering durable responses and potential long-term remission for patients with relapsed or refractory (R/R) disease who historically had limited therapeutic options. Since the first U.S. Food and Drug Administration (FDA) approvals in 2017, CAR-T therapies have expanded across multiple disease states, including diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL), mantle cell lymphoma (MCL), acute lymphoblastic leukemia (ALL), chronic lymphocytic leukemia (CLL), and multiple myeloma (MM).¹ CAR-T therapy works by genetically modifying a patient's own T cells to recognize tumor-associated antigens, enabling targeted immune-mediated destruction of malignant cells. Common commercially available constructs currently target CD19 in B-cell malignancies and B-cell maturation antigen (BCMA) in MM.²

The rapid evolution of CAR T-cell therapy has resulted in significant improvements in outcomes for patients with R/R hematologic cancers. Clinical trials and real-world evidence have demonstrated high overall response rates and meaningful survival benefits in heavily pretreated patient populations. CAR-T therapy has consequently become an integral component of modern treatment algorithms and is increasingly utilized in earlier lines of therapy for select malignancies, particularly DLBCL.³ However, despite these advances, access to CAR-T therapy remains inequitable

across practice settings and geographic regions.

Historically, CAR-T therapies were administered almost exclusively in the inpatient setting due to the risk of potentially severe toxicities, including CRS and ICANS.⁴ Advances in toxicity recognition, supportive care strategies, and earlier intervention approaches have improved the ability of oncology teams to identify and manage these events.⁵ Reflecting this growing experience, the FDA recently eliminated the Risk Evaluation and Mitigation Strategy (REMS) requirements for approved autologous BCMA- and CD19-directed CAR-T therapies while maintaining boxed warnings and other safety monitoring requirements.⁶ Although this change may reduce certain administrative requirements, CAR-T delivery still requires substantial operational coordination, multidisciplinary expertise, patient and caregiver education, and standardized monitoring processes. These requirements may remain challenging for smaller oncology practices, community cancer centers, and rural health systems seeking to develop CAR-T capabilities or expand access through coordinated care models.^{5,7}

As CAR-T utilization expands, there is growing recognition that a “one-size-fits-all” model for delivery is not feasible across the oncology care continuum. Community oncology practices and regional healthcare systems vary significantly in terms of infrastructure, staffing, geographic access to tertiary referral centers, and experience with cellular therapies. Consequently, several distinct practice archetypes have emerged to support patient access to CAR-T therapy. These include fully outpatient CAR-T programs, community practices with strong referral relationships to academic CAR-T centers, practices actively developing CAR-T capabilities and partnerships, and rural or geographically isolated sites with limited access to specialized cellular therapy centers. Each archetype faces unique operational, financial, logistical, and educational challenges that influence patient access, care coordination, toxicity management, and long-term follow-up.⁷

Improving access to CAR-T therapy has become an increasingly important priority as the majority of patients with cancer in the United States receive care within community oncology settings.⁸ Delays in referral, limited provider familiarity with eligibility criteria, financial toxicity, travel burden, caregiver requirements, and constrained inpatient capacity may all contribute to disparities in access to these potentially life-saving therapies.⁸ Furthermore, prolonged inpatient hospitalization associated with CAR-T therapy may increase healthcare resource utilization, overall costs, and patient burden.⁸ Emerging evidence suggests that appropriately selected patients may safely receive CAR-T therapy in outpatient settings, potentially reducing hospitalization

duration, improving patient satisfaction, and lowering healthcare costs when supported by robust monitoring systems and multidisciplinary care pathways.^{7,9}

Recent expert guidance from the American Society for Transplantation and Cellular Therapy (ASTCT) and other professional organizations has emphasized the importance of developing scalable, safe, and sustainable outpatient and community-based CAR-T care models.⁴ Successful implementation requires careful consideration of institutional infrastructure, staffing, toxicity management protocols, patient and caregiver education, financial planning, and coordination between referring and treating centers.⁵ As the field continues to evolve, identifying practical approaches tailored to different oncology practice environments will be essential to expanding equitable access to CAR-T therapy while maintaining high standards of patient safety and quality care.

This white paper explores four distinct CAR-T practice archetypes across the oncology care continuum, highlighting the opportunities, challenges, and operational considerations associated with each model. By examining varying approaches to referral pathways, outpatient administration, toxicity management, multidisciplinary coordination, and patient access, this paper aims to provide practical insights and strategies to support the continued expansion of CAR-T therapy into diverse oncology practice settings.

From Specialized Therapy to Coordinated Care

The delivery of CAR-T therapy is entering a new phase of evolution. Once considered a highly specialized treatment delivered almost exclusively within large academic medical centers, CAR-T is increasingly being integrated into coordinated care models that extend across community oncology practices, regional health systems, and outpatient cellular therapy programs. As utilization continues to grow, the focus has shifted from whether CAR-T can be safely administered to how organizations can develop sustainable models that improve patient access while maintaining high standards of care.^{4,5}

This evolution has prompted a broader reexamination of how CAR-T therapy is delivered across the oncology care continuum. Although treatment administration may occur at a specialized cellular therapy center, patient care extends far beyond the infusion itself. Community oncology practices frequently identify appropriate candidates, coordinate diagnostic evaluations and bridging therapy, educate patients and caregivers, collaborate with referral centers, and resume longitudinal management following treatment. As a result, CAR-T has become a shared-care

model that depends on coordinated transitions between multiple providers and care settings.

The expansion of outpatient CAR-T programs has further accelerated this transformation. Growing clinical experience has demonstrated that appropriately selected patients can be safely managed outside the inpatient setting when supported by standardized monitoring protocols and multidisciplinary care teams. As organizations gain experience, operational excellence has become just as important as clinical expertise. Efficient referral pathways, coordinated scheduling, financial navigation, patient and caregiver preparation, and timely communication across organizations all contribute to safe and successful CAR-T delivery.^{4,5}

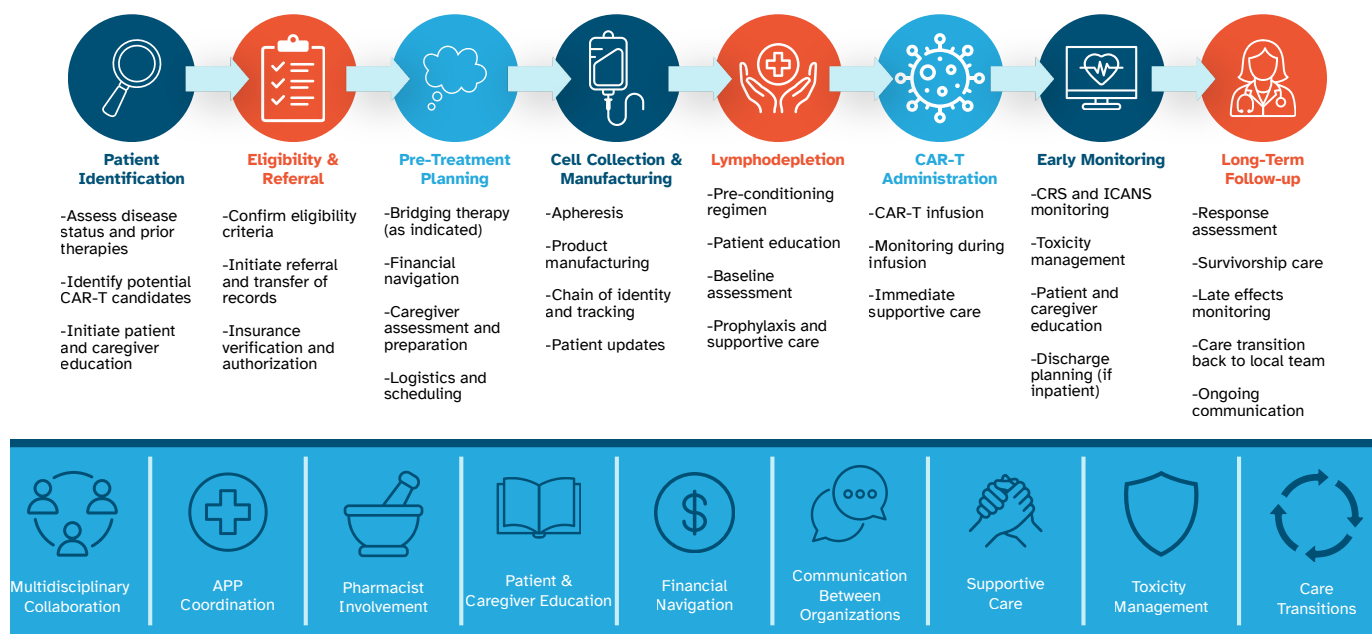
CAR-T access continues to vary significantly across practice settings and regions. Geographic location, institutional infrastructure, referral relationships, insurance requirements, transportation challenges, caregiver availability, and staffing resources all influence how and where patients receive care. These factors have led organizations to develop delivery models that reflect their unique patient populations, available resources, and strategic priorities rather than adopting a single standardized approach.

The interviews conducted for this white paper demonstrated that, while organizations differ considerably in size, structure, and operational capabilities, they often face many of the same challenges. Participants across academic medical centers, community oncology practices, outpatient CAR-T programs, and rural referral networks consistently described the need to improve referral efficiency, strengthen communication across care settings, support patients and caregivers throughout the treatment journey, and coordinate multidisciplinary teams. Although the specific workflows varied, the shared objective remained constant: providing timely access to CAR-T therapy while delivering safe, coordinated, and patient-centered care.

Rather than identifying a single best model for CAR-T delivery, the interviews highlighted that successful implementation is shaped by each organization's unique environment, resources, and patient population. The practice archetypes presented in the following sections illustrate how different organizations have adapted their operational strategies to meet these challenges, offering practical insights that can inform CAR-T implementation across a wide range of oncology settings.

FIGURE 1. THE CAR-T CARE CONTINUUM: COORDINATED CARE ACROSS DIVERSE PRACTICE MODELS

CAR-T therapy is delivered through a continuum of coordinated care. The same phases of care may occur in different settings depending on the practice model, but successful outcomes depend on seamless coordination across the entire patient journey.



CAR-T Therapy is no longer defined by where care occurs. It is defined by how care is coordinated.

Archetype 1: Formal CAR-T Referral Partnerships

Coordinated Excellence Through Mature Community-Academic Networks

Practice Snapshot

Representative Practice	Texas Oncology & Baylor University Medical Center
Model	Mature Community-Academic Referral Partnership
Primary Strength	Established referral pathways and shared care
Operational Focus	Coordinated transitions across organizations
Key Challenge	Administrative coordination between independent health systems
Key Insight	Longstanding relationships, clearly defined roles, and continuous communication enable community oncology practices and cellular therapy centers to function as a coordinated care team while preserving continuity of care.

Table 1: Practice Snapshot mature community-academic CAR-T referral partnership.

Formal referral partnerships represent one of the most established models of CAR-T delivery, demonstrating how community oncology practices and academic cellular therapy centers can work together to expand patient access while maintaining continuity of care. These partnerships are built on clearly defined referral pathways, shared clinical responsibilities, and longstanding professional relationships that allow patients to receive highly specialized therapy without becoming disconnected from their local oncology team.

The collaboration between **Texas Oncology and Baylor University Medical Center** exemplifies this approach. Although Baylor serves as the cellular therapy center, the transplant physicians are employed by Texas Oncology while practicing within Baylor, creating a coordinated model that bridges community and academic care across a large regional network.

“I physically work at Baylor University Medical Center, but I don’t work for Baylor. I work for Texas Oncology.”

— Carolina Escobar, MD, Hematologist/Oncologist and Blood & Marrow Transplant Specialist, Texas Oncology

This unique structure allows patients to benefit from the expertise and infrastructure of a high-volume cellular therapy center while maintaining continuity with their community oncology providers throughout much of the treatment journey.

Established Referral Relationships

Longstanding professional relationships create confidence in the referral process and encourage earlier patient evaluation. Rather than viewing referral as a transfer of care, participants described it as a continuation of an established partnership built on years of collaboration and mutual trust.

“Many of these (Baylor) physicians trained with our physicians...which is primarily where a majority of our referrals for CAR-T come from.”

— David Samuel, PharmD, Stem Cell Transplant Clinical Pharmacist, Texas Oncology

These trusted relationships reduce uncertainty, facilitate direct communication between providers, and help ensure that patients are referred before disease progression limits treatment options.

Continuous Communication and Shared Care

Communication extends well beyond the initial referral. Physicians, pharmacists, transplant coordinators, and community oncology teams remain connected throughout evaluation, bridging therapy, manufacturing, treatment, and transition back to the referring practice. This collaborative approach allows treatment plans to evolve as patients move through the CAR-T process while ensuring continuity between organizations.

Following CAR-T administration, community oncology practices continue to play an active role by providing laboratory monitoring, supportive care, infection surveillance, transfusion support, and long-term disease management. This shared-care model minimizes travel while allowing patients to remain connected to providers they know and trust.

Coordinated Patient and Caregiver Support

Successful partnerships extend beyond clinical coordination to include structured education and navigation throughout the patient journey. Participants described education as an ongoing process rather than a single encounter, with transplant coordinators serving as consistent points of contact from referral through recovery.

“We’re really holding their hand each step along the way.”

— Leah Josey, BSN, RN, Transplant Coordinator, Blood and Marrow Transplantation, Texas Oncology

This longitudinal approach helps patients and caregivers navigate a complex treatment process, reinforces expectations, and improves preparedness throughout each stage of care.

Operational Considerations

Even the most mature referral partnerships require continuous operational coordination. Participants emphasized that successful collaboration depends not on eliminating organizational boundaries, but on developing standardized processes that allow patients to move seamlessly between community oncology practices and cellular therapy centers.

Although clinical responsibilities are well defined, administrative activities, including referral coordination, financial clearance, scheduling, admissions, and transitions back to the referring practice, require ongoing communication between organizations. Dedicated transplant coordinators, pharmacists, financial counselors, and physician teams

play a critical role in ensuring that these behind-the-scenes activities remain invisible to patients, allowing the care experience to feel coordinated despite occurring across multiple institutions.

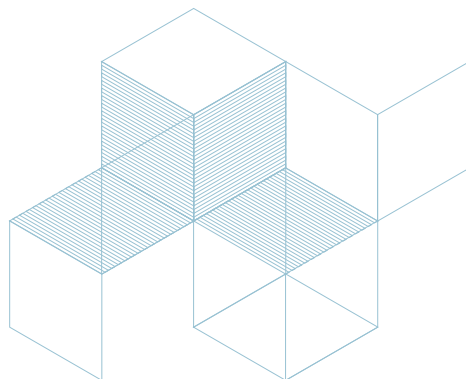
Participants also noted that many of the greatest barriers to timely CAR-T therapy exist outside of the healthcare system itself. Caregiver availability, transportation, temporary lodging, insurance authorization, and geographic distance continue to influence treatment timelines, even within highly coordinated referral networks. Successfully addressing these challenges requires proactive planning and collaboration among the multidisciplinary care team.

Rather than viewing these operational complexities as limitations, mature referral partnerships have developed workflows that anticipate and manage them. Their experience demonstrates that strong relationships, clearly defined responsibilities, and consistent communication can overcome many of the logistical challenges associated with delivering CAR-T therapy across independent organizations.

Lessons Learned

The Texas Oncology–Baylor partnership demonstrates that successful CAR-T referral networks are built on more than standardized workflows. Longstanding professional relationships, shared accountability, and continuous communication enable community oncology practices and cellular therapy centers to function as a coordinated care team rather than independent organizations.

Although operational complexity remains, mature referral partnerships illustrate how clearly defined roles, collaborative decision making, and intentional transitions of care can improve referral efficiency, preserve continuity, and expand patient access to CAR-T therapy. As more organizations seek to strengthen community–academic collaboration, this model provides a practical framework for building sustainable, patient-centered CAR-T programs.



Archetype 2: Emerging Referral Networks

Building Sustainable Community-Based CAR-T Programs

Practice Snapshot	
Representative Practice	Cancer Specialists of North Florida
Model	Community oncology practice developing an outpatient CAR-T program while maintaining regional referral relationships
Primary Strength	Intentional development of governance, SOPs, and multidisciplinary infrastructure before program launch
Operational Focus	Building sustainable workflows, external partnerships, and internal operational readiness
Key Challenge	Coordinating implementation across multiple external partners while maintaining timely patient access
Key Insight	Successful CAR-T implementation begins long before the first patient is treated, requiring strategic planning, collaboration, and continuous communication.

Table 2. Practice Snapshot: Emerging Community-Based CAR-T Program

As CAR-T therapy continues to expand beyond traditional academic medical centers, many community oncology practices are transitioning from referring patients to actively developing their own CAR-T capabilities. These organizations often begin by establishing referral relationships with experienced cellular therapy centers while simultaneously building the governance, operational infrastructure, and multidisciplinary expertise needed to safely deliver CAR-T closer to home. Unlike mature referral partnerships, emerging programs are defining workflows in real time, relying on collaboration, education, and continuous process improvement to guide implementation.

Cancer Specialists of North Florida (CSNF) represents this evolving model. While continuing to refer appropriate patients to regional CAR-T centers, the practice is developing an outpatient CAR-T program designed to improve access for patients who face geographic, logistical, or insurance-related barriers to treatment.

Expanding Access Through Program Development

For CSNF, the decision to build an outpatient CAR-T program was driven by a simple observation: many eligible patients were unable or unwilling to travel to distant treatment centers, resulting in alternative therapies being selected despite CAR-T representing the preferred treatment option.

“A lot of our patients decline to travel that far. They say, ‘I know you’re recommending CAR-T, but I don’t want to do it.’ So, we end up doing alternative therapy options such as bispecifics...or other standard-of-care therapies.”

— Ayed Ayed, MD, Hematologist/Oncologist, Cancer Specialists of North Florida

This experience reinforced the need to bring advanced cellular therapies closer to the community while maintaining the safety and quality standards required for successful implementation.

Building the Infrastructure Before the First Patient

Participants consistently emphasized that successful implementation begins well before treating the first patient. CSNF has established a multidisciplinary Cellular Therapeutics Committee responsible for clinical review, developed standardized screening and financial approval processes, and created Standard Operating Procedures (SOPs) to guide patient care from referral through treatment.

“There are so many moving parts and a lot of collaboration with outside associates...we have worked really hard on developing the SOPs. We just need to get approval on the policy, and then everybody needs to read it, understand it, and be able to follow these rules and regulations.”

— Joyce Wong, MD, Clinical Operations Manager, Cancer Specialists of North Florida

Rather than viewing implementation as a single milestone, participants described it as a deliberate process of building systems that can reliably support outpatient CAR-T delivery.

Developing Strong External Partnerships

Because many components of CAR-T delivery require collaboration beyond the oncology practice, participants highlighted the importance of identifying reliable external partners early in the implementation process. Establishing relationships for apheresis services, hospital support, manufacturer onboarding, and financial coordination requires extensive planning before a program becomes operational.

“Our biggest hurdle has been coordinating everybody at the same time...trying to find different partners to work with and how that would look for our patients.”

— Michael Seppelfrick, PharmD, Pharmacist, Cancer Specialists of North Florida

Participants also emphasized the value of learning from established CAR-T programs through OneOncology, pharmaceutical manufacturers, and experienced community practices, allowing them to anticipate challenges and adapt proven workflows to their own environment.

Operational Considerations

As emerging referral networks transition toward independent CAR-T delivery, participants identified communication and operational coordination as essential to success. While established relationships with referral centers remain important, building internal governance, defining responsibilities, and coordinating across multiple external partners require sustained multidisciplinary effort.

Dr. Ayed emphasized that the quality of a referral relationship is determined not only by clinical expertise, but also by responsiveness and communication.

“When you know that, yes, for sure they will evaluate the patient, they will let you know whether they’re a good candidate or not, that is what makes a referral process streamlined and makes it more favorable.”

— Ayed Ayed, MD

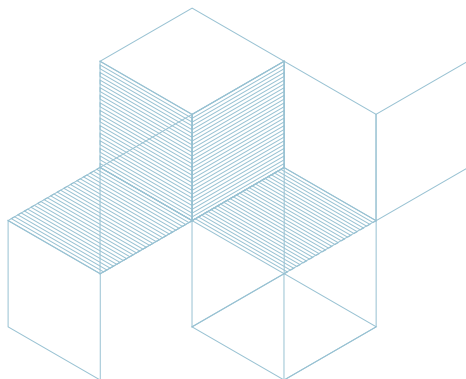
He also noted that timely acknowledgment of referrals and bidirectional communication remain critical to maintaining confidence in the referral process.

These insights demonstrate that, even as organizations develop their own CAR-T capabilities, strong communication between referring providers, treatment centers, and multidisciplinary teams remains fundamental to coordinated patient care.

Lessons Learned

The CSNF experience demonstrates that developing a successful CAR-T program extends well beyond clinical readiness. Establishing governance structures, standardized workflows, external partnerships, and multidisciplinary communication creates the operational foundation needed to safely expand access to cellular therapy within the community setting.

While emerging programs continue to refine their processes, they also illustrate an important shift in oncology care: community practices are no longer simply referring patients for CAR-T, they are actively developing the infrastructure needed to deliver these therapies closer to home. By building strong partnerships, investing in operational readiness, and maintaining a patient-centered focus, these organizations are helping reshape how CAR-T therapy will be delivered in the future.



Archetype 3: Fully Outpatient CAR-T Programs

Redesigning CAR-T Delivery Beyond the Hospital

Practice Snapshot	
Representative Practice	New York Oncology Hematology (Community) and Moffitt Cancer Center (Academic)
Model	Fully outpatient CAR-T programs supported by standardized monitoring and multidisciplinary care
Primary Strength	Comprehensive care coordination that enables safe outpatient treatment while maintaining rapid access to higher levels of care
Operational Focus	Standardized SOPs, patient and caregiver education, intensive monitoring, and multidisciplinary communication
Key Challenge	Scaling outpatient capacity while maintaining dedicated staffing, consistent communication, and operational efficiency
Key Insight	Successful outpatient CAR-T programs are built by redesigning the care delivery model around proactive monitoring, multidisciplinary coordination, and rapid response—not simply by moving treatment from the hospital to the clinic.

Table 3. Practice Snapshot: Fully Outpatient CAR-T Programs

Historically, CAR-T therapy was delivered almost exclusively in the inpatient setting because of concerns surrounding CRS, ICANS, and the need for close monitoring. As experience with cellular therapies has grown, several organizations have demonstrated that appropriately selected patients can be safely treated in the outpatient setting when supported by standardized clinical pathways, dedicated multidisciplinary teams, and robust monitoring systems. Although community oncology practices and academic medical centers differ considerably in size and organizational structure, participants consistently described remarkably similar approaches to outpatient CAR-T delivery.

The experiences of **New York Oncology Hematology (NYOH)** and **Moffitt Cancer Center** illustrate that successful outpatient CAR-T programs are built on intentional care redesign rather than simply changing the site of treatment. Both organizations emphasized standardized workflows, intensive patient and caregiver education, continuous communication, and clearly defined escalation pathways that allow patients to remain safely outside the hospital while maintaining immediate access to specialized care when needed.

Building an Outpatient Model Around the Patient

For both organizations, improving patient access and experience was a primary motivation for developing outpatient CAR-T programs. Rather than requiring prolonged hospital-

ization, outpatient care allows patients to recover in a more familiar environment while remaining under close clinical observation.

“Our mission is always world-class care close to home. Knowing that CAR-T was going to be the future was what really drove our decision.”

— Courtney Bellomo, MD, Hematologist/Oncologist, New York Oncology Hematology

Similarly, Moffitt’s outpatient program evolved in response to increasing patient demand and limited inpatient capacity.

“We moved from about 25 patients...to nearly 385 patients per year. Trying to manage all those patients in a unit with only 12 inpatient beds became more complicated.”

— Omar Castaneda Puglianini, MD, Hematologist/Oncologist, Moffitt Cancer Center

Participants emphasized that outpatient delivery was not simply intended to reduce hospitalizations, but to improve access while maintaining the same high standards of patient safety.

Standardized Processes Enable Safe Outpatient Care

Both organizations stressed that successful outpatient CAR-T programs depend upon standardized operational

processes developed long before the first patient is treated. Clinical protocols clearly define patient eligibility, monitoring schedules, toxicity management, communication pathways, and responsibilities across the multidisciplinary team.

“We needed to have everything protocolized.”

— Omar Castaneda Puglianini, MD

Rather than implementing outpatient CAR-T all at once, Moffitt introduced the program gradually, beginning with selected products and carefully evaluating outcomes before expanding eligibility. This deliberate approach allowed the team to refine workflows, educate staff, and build confidence while maintaining patient safety.

Communication Becomes the Safety Net

Participants consistently identified communication as the foundation of successful outpatient CAR-T care. Frequent patient assessments, standardized documentation, multidisciplinary collaboration, and continuous communication allow care teams to identify potential complications early and intervene rapidly when needed.

Patient and caregiver education was viewed as equally important. Rather than relying on continuous remote monitoring technology, organizations emphasized teaching patients and caregivers to recognize early symptoms and providing direct access to the clinical team at any time.

“Education is the first safeguard.”

— Omar Castaneda Puglianini, MD

Mary Jo Tomlinson, RN, further described the intensity of outpatient monitoring during the highest-risk period:

“If we find any indications of CRS or ICANS, we try to manage it at home. If we cannot, we bring them back into the clinic regardless of time of day.”

— Mary Jo Tomlinson, RN, OCN, Cellular Therapy Nursing Supervisor, New York Oncology Hematology

This combination of structured monitoring, caregiver engagement, and continuous access to experienced clinicians allows many patients to remain safely outside the hospital while ensuring timely recognition of CRS, ICANS, and other complications.

Operational Considerations

Although outpatient CAR-T has expanded access and reduced dependence on inpatient beds, participants emphasized that it does not reduce operational complexity.

Instead, many traditional inpatient responsibilities shift to the outpatient setting, requiring dedicated staffing, multidisciplinary coordination, and clearly defined escalation pathways.

Participants described the importance of experienced nurses, APPs, pharmacists, physicians, treatment coordinators, financial specialists, and administrative staff working as a highly coordinated team.

“It pretty much takes a village. You’ve got nursing, you’ve got the billers, contracting...getting your team together from the beginning is essential because that’s the only thing that’s going to make the journey easier.”

— Kathy Preville, Managed Care Contracting/Credentialing Manager, New York Oncology Hematology

In addition to clinical readiness, participants emphasized that financial planning and payer engagement are essential to successful outpatient CAR-T delivery. Because these therapies represent a significant financial investment, practices described the importance of establishing payer contracts, obtaining timely prior authorization, and developing reimbursement strategies that support the operational costs of treatment. Participants noted that sustainable outpatient CAR-T programs require close collaboration among clinical teams, managed care contracting, financial specialists, and administrative leadership to ensure both patient access and program viability.

“You have to have the right contracts in place. You certainly cannot invest in a half-million-dollar drug and all the overhead associated with taking care of the patient if you are underwater.”

— Nancy Egerton, PharmD, BCOP, Pharmacist, New York Oncology Hematology

Hospital partnerships remain essential to support patients requiring admission for toxicity management, while standardized SOPs and ongoing education help maintain consistency as programs continue to grow.

As Dr. Castaneda advised organizations considering outpatient CAR-T:

“I think it’s very doable...but you have to train different groups of people and create an SOP so everybody knows what to do.”

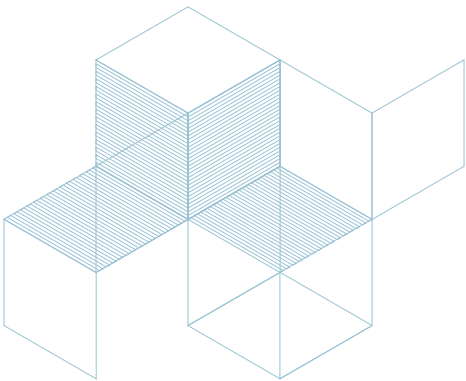
— Omar Castaneda Puglianini, MD

Lessons Learned

The experiences of NYOH and Moffitt demonstrate that successful outpatient CAR-T programs are defined not by

the absence of hospitalization, but by the strength of the systems supporting patients outside the hospital. Standardized workflows, multidisciplinary collaboration, comprehensive patient and caregiver education, and rapid communication pathways allow organizations to safely expand outpatient CAR-T while maintaining high-quality care.

Although community and academic practices differ in structure and resources, both organizations arrived at remarkably similar conclusions: successful outpatient CAR-T depends less on practice setting than on thoughtful program design, operational discipline, and a coordinated multidisciplinary team committed to proactive patient management.



Archetype 4: Rural and Geographically Isolated Cancer Centers

Expanding Access Through Coordinated Referral Networks

Practice Snapshot

Representative Practice	WVU Cancer Institute, Wheeling Hospital
Model	Regional hospital-based cancer center within a rural health system utilizing coordinated referral partnerships with tertiary CAR-T centers
Primary Strength	Strong physician-to-physician collaboration and shared-care approach supporting continuity before and after CAR-T
Operational Focus	Early patient identification, referral coordination, communication across organizations, and local post-treatment follow-up
Key Challenge	Transportation, caregiver availability, geographic distance, payer restrictions, and maintaining communication across multiple health systems
Key Insight	Rural practices remain essential partners in the CAR-T care continuum by identifying appropriate patients early, coordinating referrals, and providing ongoing care close to home, demonstrating that access depends as much on collaboration as on geography.

Table 4. Practice Snapshot: Rural and Geographically Isolated Referral Networks

For many rural and geographically isolated cancer centers and hospital-based oncology programs, CAR-T therapy is not limited by clinical expertise, but by geography and infrastructure. Although these practices may not administer CAR-T locally, they play a critical role in identifying eligible patients, initiating referrals, preparing patients for treatment, coordinating care with tertiary centers, and providing long-term follow-up after patients return home. Participants emphasized that rural practices should not be viewed as peripheral to the CAR-T journey. Rather, they serve as essential regional partners, identifying appropriate patients, coordinating referrals, supporting patients before and after treatment, and maintaining continuity of care throughout the CAR-T journey.

The experiences shared by **West Virginia University Cancer Institute, Wheeling Hospital** demonstrate that successful rural referral models rely on strong relationships with regional cellular therapy centers, clear communication, and shared responsibility across organizations. While patients often travel significant distances for CAR-T therapy, much of their ongoing oncology care continues to occur within their local community.

Distance Influences More Than Travel

Participants consistently described geography as one of the greatest challenges facing rural patients. Travel frequent-

ly requires extended time away from home, temporary relocation near the treating center, caregiver availability, and reliable transportation. These logistical demands may influence treatment decisions as much as clinical eligibility.

“I do have a good number of patients who literally don’t have a caregiver and who have significant transportation issues... I’ve had patients, particularly my older patients with myeloma, decline CAR-T on their own because of the distance.”

— Bhavana (Tina) Bhatnagar, DO, Hematologist/Oncologist, West Virginia University Cancer Institute, Wheeling Hospital

She noted that while many patients are clinically appropriate candidates, caregiver requirements, transportation challenges, and temporary relocation can become deciding factors when considering referral.

Shared Care Extends Beyond the Referral

Although CAR-T treatment occurs at tertiary centers, participants emphasized that the local oncology team remains actively involved throughout the patient’s journey. Referral begins with direct physician-to-physician communication to discuss timelines and treatment planning, followed by ongoing collaboration throughout treatment and after patients return home.

“Usually when they are done with the CAR-T, I get another phone call... They tell me what product they received, how they did, what side effects they had, and what needs to be done over the next six months. Then we start arranging the monitoring and supportive care.”

— Bhavana (Tina) Bhatnagar, DO

This shared-care approach allows patients to receive specialized cellular therapy at an experienced center while continuing much of their longitudinal oncology care closer to home.

Communication Bridges Geographic Distance

Participants consistently emphasized that communication is the foundation of successful rural referral networks. Physicians, pharmacists, nurse navigators, and administrators described regular conversations between referring and treating centers to coordinate treatment, monitor patient progress, and ensure smooth transitions back to local care.

“Communication between small and large centers helps a ton... involving each clinic pharmacist and each provider helps make sure that everything is touched on.”

— Matt Hartline, PharmD, Clinical Pharmacist, West Virginia University Cancer Institute, Wheeling Hospital

Despite strong collaboration, participants acknowledged opportunities to further improve multidisciplinary communication, particularly as patient volumes continue to increase.

“For these complex patients, we should have perhaps a weekly meeting... so we can touch base and say, ‘These are the patients and these are the updates.’”

— Maria Diaz-Chatlak, MSN, RN, OCN, Nurse Manager, West Virginia University Cancer Institute, Wheeling Hospital

Looking Toward the Future

Rather than viewing referral as the endpoint, participants described it as the foundation for future program development. As CAR-T indications continue to expand, organizations such as WVU Wheeling Hospital are investing in new facilities, workforce development, and operational planning with the goal of bringing advanced cellular therapies closer to patients throughout the region they serve.

Participants also recognized that emerging innovations, including streamlined manufacturing processes and future off-the-shelf cellular therapies, may further reduce barriers to community-based delivery. Until then, strengthening referral pathways, standardizing communication, and expanding collaboration between community and tertiary centers remain essential strategies for improving equitable access.

Lessons Learned

The experiences of WVU Wheeling Hospital demonstrate that expanding access to CAR-T therapy does not always require delivering the therapy locally. Rural hospital-based cancer centers play a vital role by recognizing eligible patients early, facilitating timely referrals, coordinating care across organizations, and supporting patients after they return home. While geography, transportation, caregiver availability, and payer restrictions remain significant barriers, strong partnerships and consistent communication allow rural practices to remain integral members of the multidisciplinary CAR-T care team.

Building Successful CAR-T Programs: Shared Insights Across Practice Settings

Although the organizations highlighted in this white paper represent diverse practice settings, each has developed approaches that reflect its available resources, patient population, and institutional capabilities. Rather than identifying a single optimal model for CAR-T delivery, these interviews demonstrate that successful programs are built by adapting common operational principles to the realities of each practice environment.

The following lessons emerged consistently across interviews and may help organizations strengthen existing programs or prepare for future expansion of CAR-T services.

Early Identification Creates Opportunity

Successful CAR-T programs begin long before referral or treatment. Participants consistently emphasized the importance of identifying potentially eligible patients early enough to allow time for referral, insurance authorization, caregiver planning, disease assessment, and coordination with the treating center.

As indications continue to expand into earlier lines of therapy, proactive identification will become increasingly important. Timely referral can help preserve treatment options and provide the care team with adequate time to plan for bridging therapy, when clinically appropriate, as well as address logistical considerations that may otherwise limit patient access.

Operational Readiness Begins Before the First Patient

Practices developing CAR-T programs consistently described implementation as an operational initiative rather than simply adding a new therapy. Developing SOPs, establishing multidisciplinary governance, educating staff, defining communication pathways, and creating standardized workflows all occurred before treating the first patient.

Organizations with established outpatient programs similarly emphasized that standardized processes continue to evolve as new products, indications, and operational requirements emerge. Successful implementation was viewed as an ongoing process of refinement rather than a single milestone.

Communication Sustains Shared Care

Whether participants represented referral practices, outpatient CAR-T centers, or rural hospital systems, communication consistently emerged as one of the strongest determinants of successful care coordination.

Participants described multiple approaches to maintaining continuity, including physician-to-physician discussions, pharmacist collaboration, nurse navigator outreach, multidisciplinary meetings, standardized care plans, and direct communication during transitions back to the local oncology team. Regardless of the mechanism used, participants agreed that timely, bidirectional communication strengthens referral relationships, improves continuity of care, and helps ensure patients receive consistent support throughout the treatment journey.

Patients and Caregivers Require Continuous Preparation

Participants consistently described patient education as a longitudinal process rather than a single educational encounter. Preparing patients for CAR-T extends beyond explaining the treatment itself and includes setting expectations regarding caregiver responsibilities, temporary relocation, monitoring requirements, symptom recognition, and the overall treatment timeline.

Several organizations noted that travel, caregiver availability, and logistical considerations frequently influence treatment decisions. Early discussions about these factors allow care teams to proactively identify barriers and connect patients with available support services before they become obstacles to treatment.

Program Growth Requires Investment Beyond Clinical Expertise

Expanding access to CAR-T requires more than clinical knowledge. Participants described the need for dedicated personnel, administrative support, financial coordination, scheduling infrastructure, pharmacy involvement, nursing resources, and ongoing education to sustain successful programs.

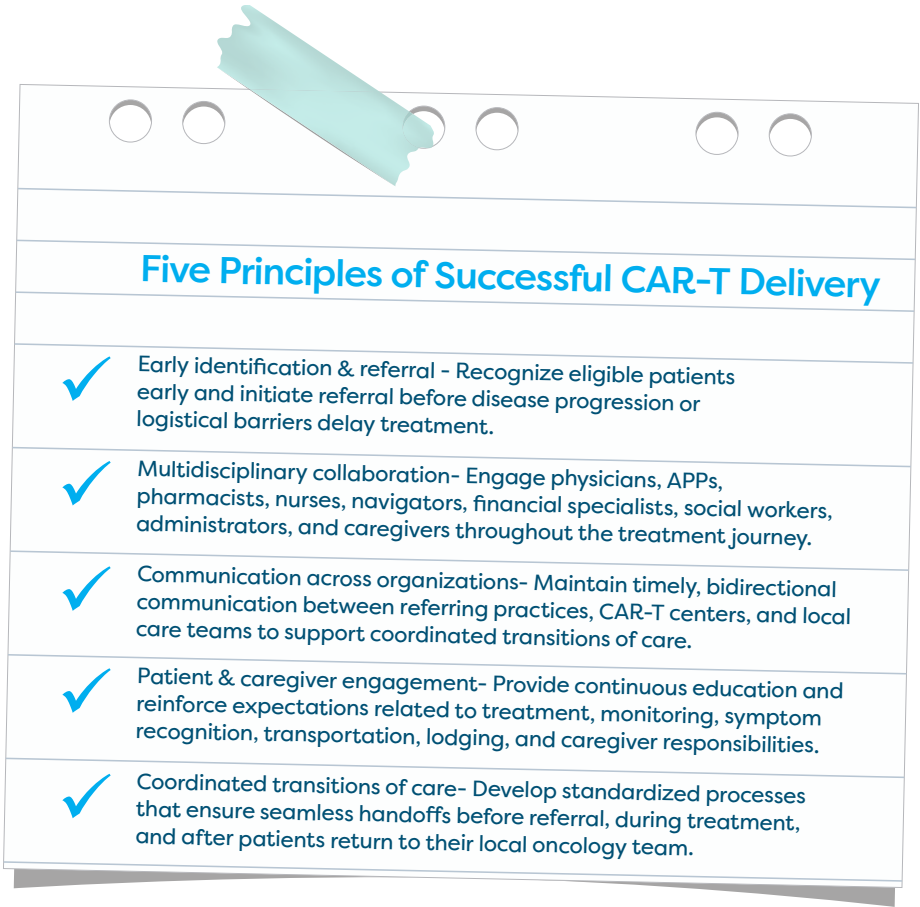
Regardless of practice setting, organizations recognized that investments in operational infrastructure ultimately improve efficiency, strengthen multidisciplinary coordination, and position programs to accommodate future growth as CAR-T utilization continues to expand.

Looking Ahead

The experiences shared throughout this white paper demonstrate that CAR-T delivery will continue to evolve across a broad range of oncology practice settings. Community practices are developing new referral partnerships and outpatient capabilities, academic centers continue to refine high-volume outpatient models, and regional hospital systems are investing in the infrastructure needed to

improve access closer to home.

Future advances in cellular therapy, including simplified manufacturing processes, evolving reimbursement models, and next-generation products, may further expand opportunities for community-based delivery. However, participants consistently emphasized that the greatest opportunity lies not in any single technological advancement, but in strengthening the systems that support patients throughout



Five Principles of Successful CAR-T Delivery

- ✓ Early identification & referral - Recognize eligible patients early and initiate referral before disease progression or logistical barriers delay treatment.
- ✓ Multidisciplinary collaboration- Engage physicians, APPs, pharmacists, nurses, navigators, financial specialists, social workers, administrators, and caregivers throughout the treatment journey.
- ✓ Communication across organizations- Maintain timely, bidirectional communication between referring practices, CAR-T centers, and local care teams to support coordinated transitions of care.
- ✓ Patient & caregiver engagement- Provide continuous education and reinforce expectations related to treatment, monitoring, symptom recognition, transportation, lodging, and caregiver responsibilities.
- ✓ Coordinated transitions of care- Develop standardized processes that ensure seamless handoffs before referral, during treatment, and after patients return to their local oncology team.

the treatment journey. Organizations that invest in multidisciplinary collaboration, standardized operational processes, strong referral relationships, and coordinated transitions of care will be best positioned to safely expand access while maintaining high-quality, patient-centered care.

The experiences shared across all four archetypes consistently reinforced five foundational principles that support successful CAR-T implementation regardless of practice setting

Conclusion

The continued expansion of CAR-T therapy represents more than the adoption of a highly specialized treatment; it reflects a broader transformation in how oncology care is co-

ordinated across healthcare systems. As indications expand and more patients become eligible for cellular therapy, success will increasingly depend on the ability of organizations to work beyond traditional institutional boundaries, integrating expertise, resources, and shared accountability throughout the patient journey.

The experiences presented in this white paper demonstrate that practices do not need to look alike to achieve the same goal. Some organizations have built sophisticated outpatient CAR-T programs, others have developed mature referral partnerships, and many are still laying the operational foundation needed to expand access. Each model contributes to the same objective: ensuring that patients receive timely, safe, and coordinated care regardless of where they enter the healthcare system.

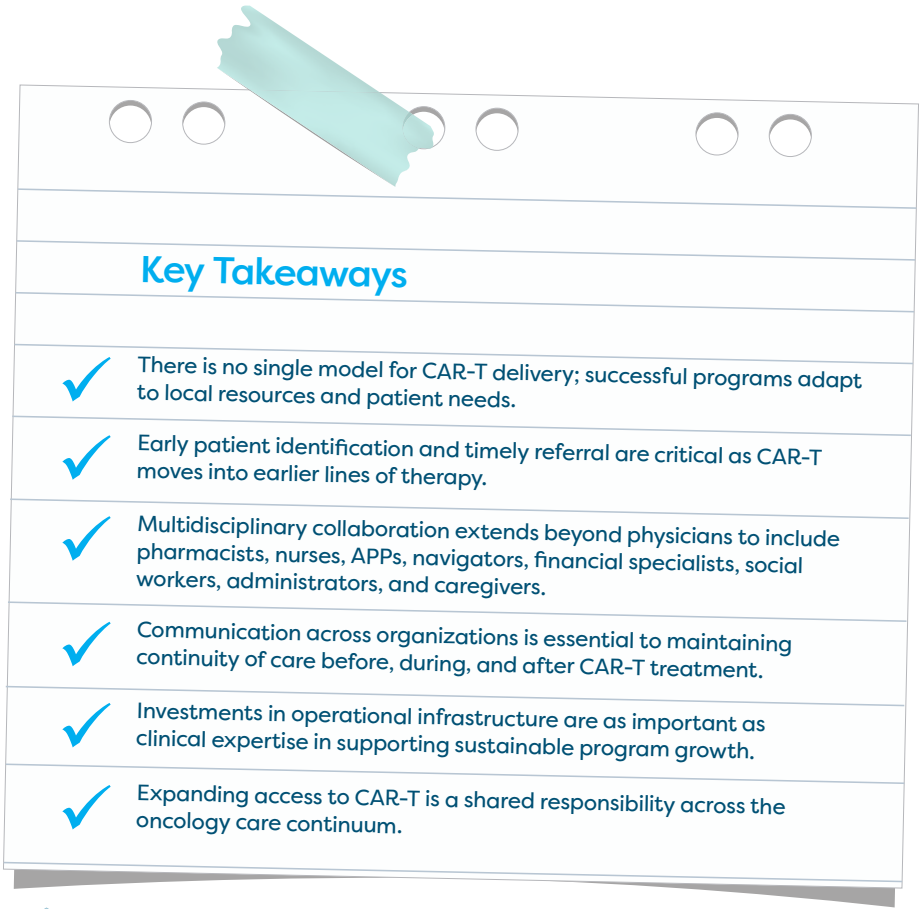
Perhaps the most important finding from these interviews

is that access to CAR-T is no longer defined solely by the centers that administer the therapy. Referring oncologists, regional hospital systems, pharmacists, APPs, nurses, navigators, financial specialists, and caregivers all play essential roles in determining whether a patient ultimately reaches treatment and successfully returns to their local oncology team. Expanding access therefore requires strengthening the entire care continuum rather than focusing on a single point of care.

As cellular therapies continue to evolve, practices will undoubtedly adopt new technologies, operational models, and treatment approaches. However, the organizations best positioned for future success will be those that contin-

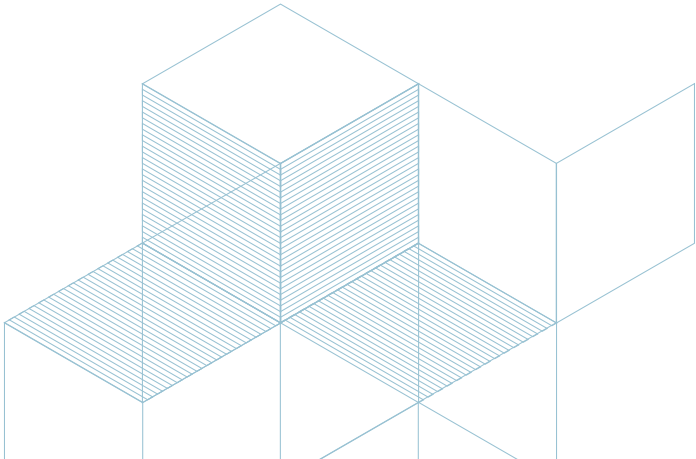
ue to invest in relationships as intentionally as they invest in infrastructure. Strong partnerships, shared communication, multidisciplinary collaboration, and patient-centered coordination will remain the foundation upon which sustainable CAR-T programs are built.

Ultimately, the future of CAR-T is not simply about expanding where treatment is delivered. It is about creating a connected oncology ecosystem in which every practice, regardless of size, geography, or experience, can contribute meaningfully to delivering advanced cellular therapies. By strengthening collaboration across the oncology community, practices can help ensure that more patients benefit from these transformative treatments.



Key Takeaways

- ✓ There is no single model for CAR-T delivery; successful programs adapt to local resources and patient needs.
- ✓ Early patient identification and timely referral are critical as CAR-T moves into earlier lines of therapy.
- ✓ Multidisciplinary collaboration extends beyond physicians to include pharmacists, nurses, APPs, navigators, financial specialists, social workers, administrators, and caregivers.
- ✓ Communication across organizations is essential to maintaining continuity of care before, during, and after CAR-T treatment.
- ✓ Investments in operational infrastructure are as important as clinical expertise in supporting sustainable program growth.
- ✓ Expanding access to CAR-T is a shared responsibility across the oncology care continuum.



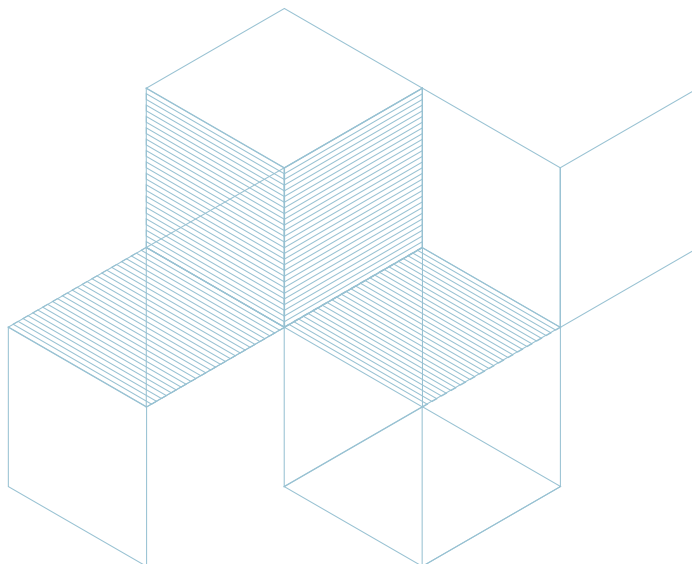
REFERENCES:

1. Perez A, Al Sagheer T, Nahas GR, Linhares YPL. Outpatient administration of CAR T-cell therapy: a focused review with recommendations for implementation in community-based centers. *Front Immunol.* 2024;15:1412002. Published 2024 May 8. doi:10.3389/fimmu.2024.1412002
2. Dabas P, Danda A. Revolutionizing cancer treatment: a comprehensive review of CAR-T cell therapy. *Med Oncol.* 2023;40(9):275. Published 2023 Aug 22. doi:10.1007/s12032-023-02146-y
3. Epperla N, Kumar A, Abutalib SA, et al. ASTCT Clinical Practice Recommendations for Transplantation and Cellular Therapies in Diffuse Large B Cell Lymphoma. *Transplant Cell Ther.* 2023;29(9):548-555. doi:10.1016/j.jtct.2023.06.012
4. Oluwole OO, Dholaria B, Knight TE, et al. Chimeric Antigen Receptor T-Cell Therapy in the Outpatient Setting: An Expert Panel Opinion from the American Society for Transplantation and Cellular Therapy. *Transplant Cell Ther.* 2024;30(2):131-142. doi:10.1016/j.jtct.2023.11.008
5. Gatwood K, Mahmoudjafari Z, Baer B, et al. Outpatient CAR T-Cell Therapy as Standard of Care: Current Perspectives and Considerations. *Clin Hematol Int.* 2024;6(2):11-20. Published 2024 Apr 9. doi:10.46989/001c.115793
6. U.S. Food and Drug Administration. FDA Eliminates Risk Evaluation and Mitigation Strategies (REMS) for Autologous Chimeric Antigen Receptor T Cell Immunotherapies. U.S. Food and Drug Administration, 2025, <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor>.
7. Simmons GL, Cross S, Pittos EC. Advancing access to CAR T-cell therapy: insights and real-world experience from a community oncology practice. *Front Oncol.* 2026;16:1712533. Published 2026 Feb 16. doi:10.3389/fonc.2026.1712533
8. Furqan F, Bhatlapenumarthy V, Dhakal B, et al. Outpatient administration of CAR T-cell therapies using a strategy of no remote monitoring and early CRS intervention. *Blood Adv.* 2024;8(16):4320-4329. doi:10.1182/bloodadvances.2024013239
9. Patel AR, Hasegawa K, Pandya S, et al. Health care resource utilization and costs of patients with diffuse large B-cell lymphoma receiving chimeric antigen receptor T-cell therapies across different settings of care: A real-world data analysis. *J Manag Care Spec Pharm.* 2025;31(11):1110-1122. doi:10.18553/jmcp.2025.31.11.1110

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This white paper was developed by NCODA in partnership with Legend Biotech. The content and conclusions represent the independent perspectives of NCODA and the participating contributors.



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This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

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