ADVANCING CUTTING-EDGE CAR-T CELL & GENE THERAPIES

Innovative Partnerships to Reduce Costs and Accelerate Access

CGT HEALTHCARE

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CAR-T Cell and Gene therapy is the future of cancer treatment, and as physicians, we must do everything in our power to increase patient access to these groundbreaking therapies"

- Andrew Branagan, MD, PhD
Medical Laboratory Director


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WHAT IS CAR-T THERAPY?

Chimeric **A**ntigen **R**eceptor **T** cell **Therapy**

Adapting the Human Immune System to Target and Treat Certain Cancers

Autologous chimeric antigen receptor (CAR) T cell therapy is breakthrough treatment for certain types of blood cancers. The treatment involves isolating a person's own immune cells and manufacturing them to recognize and kill target antigens on the cancer cells of interest. A patient's T-cells are modified with the CAR gene, which then causes the T-cell to express the chimeric antigen receptor. These engineered CAR-T cells are then multiplied in the lab by the millions and reinfused back into the patient's bloodstream. The T-cells then locate and kill cancer cells with the target antigen, and when successful, offer lasting remission rates that are higher than existing cancer treatments.

Brand name	Generic Name	Antigen	Target Cancer	Demographic
KYMRIAH (tisagenlecleucel)	Tisagenlecleucel	CD19	B-Cell acute lymphoblastic leukemia (ALL)	Patients up to 25 years old with B-Cell acute lymphoblastic leukemia (ALL) in refractory or relapsed state
			B-cell non-Hodgkin lymphoma (NHL)	Adults with B-Cell NHL in refractory or relapsed state
YESCARTA (axicabtagene ciloleucel)	Axicabtagene ciloleucel	CD19	B-cell non-Hodgkin lymphoma (NHL)	Adults with B-Cell NHL in refractory or relapsed state
			Follicular lymphoma	Adults with follicular lymphoma in refractory or relapsed state
TECARTUS (brexucabtagene autoleucel)	Brexucabtagene autoleucel	CD19	Mantle cell lymphoma	Adults with MCL in refractory or relapsed state
			B-Cell acute lymphoblastic leukemia (ALL)	Adults with B-cell ALL in refractory or relapsed state
Breyanzi (lisocabtagene maraleucel)	Lisocabtagene maraleucel	CD19	B-cell non-Hodgkin lymphoma (NHL)	Adults with B-Cell NHL in refractory or relapsed state
Abecma (idecabtagene vicleucel)	Idecabtagene vicleucel	BCMA	Multiple myeloma	Adults with multiple myeloma in refractory or relapsed state
CARVYKTI (ciltacabtagene autoleucel)	Ciltacabtagene autoleucel	BCMA	Multiple myeloma	Adults with multiple myeloma in refractory or relapsed state

Figure 1. Current FDA approved CAR-T Therapies [1]

TYPES OF CAR-T THERAPIES

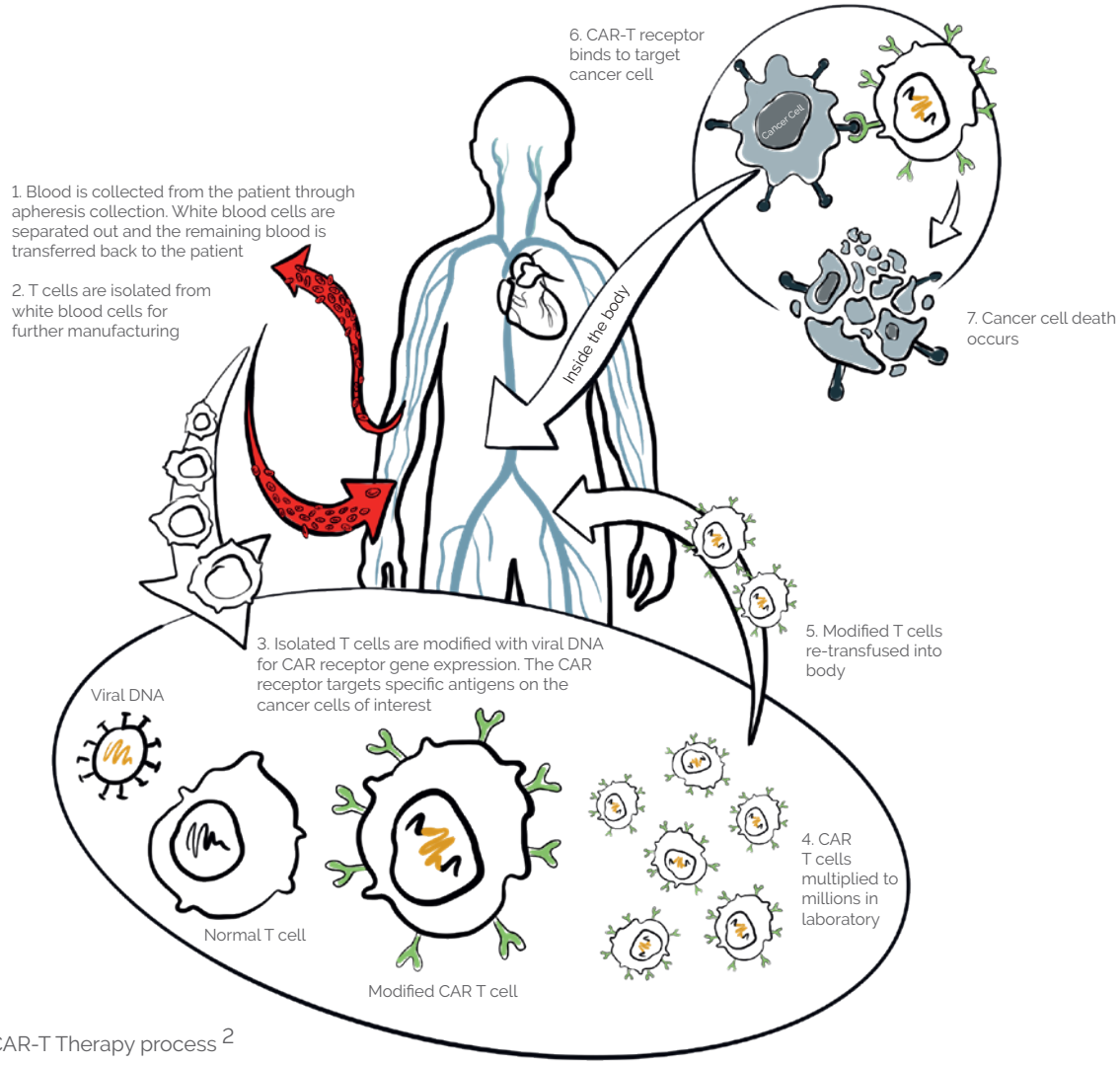


Figure 2. CAR-T Therapy process [2]

Types of CAR-T Therapies

KEY:
ALL : acute lymphoblastic leukemia
AML: acute myeloid leukemia
BCMA: B-cell maturation antigen
CLL: chronic lymphocytic leukemia
HLL: Hodgkin lymphoma
Igk: immunoglobulin kappa light chain
NHL: non-Hodgkin lymphoma
NKG2D-L: natural killer group 2D-ligands
ROR 1: receptor tyrosine kinase-like orphan receptor

Figure 3. Chimeric antigen receptor target antigens [2]

Antigen	Hematologic Malignancy
CD19	ALL, CLL, NHL, HL
CD20	CLL, NHL
CD22	ALL, NHL
Idκ	CLL, NHL, myeloma
ROR1	CLL, NHL
CD30	NHL, HL
CD138	Myeloma
CD123	AML
NKG2D-L	AML, myeloma
BCMA	Myeloma
Lewis-Y carbohydrate	AML, myeloma

CGT HEALTHCARE - THE MISSING LINK

Accelerating CAR-T Therapy Timelines

With CAR-T therapy, time is of the essence. As more therapies move to approval stages, the need for a streamlined collection, manufacturing and re-transfusion process is imminent. One strategy to speed up CAR-T timelines is to develop a more efficient manufacturing process that can produce large quantities of CAR-T Cells in a shorter time frame. Additionally, researchers are investigating ways to streamline the regulatory approval process, which can cause significant bottlenecks. With these strategies in place, researchers hope to accelerate this process, allowing more patients to benefit from this promising new treatment option.

In an effort to accelerate the apheresis and manufacturing steps, CGT Healthcare offers patient intake for apheresis collections at strategically located clinics across the nation - providing clinical grade Leukopaks ready for CAR-T manufacturing and re-infusion. We can house and operate cell manufacturing equipment under the hospital's regulatory compliance to alleviate the need for cumbersome laboratory equipment in confined hospital settings. CGT Healthcare is strategically located in close proximity to major healthcare and biotech spheres to allow for greater patient access, and rapid turnaround times from point of collection to re-infusion eliminating the costly logistics in between.

The manufacturing process for FDA-approved CAR-T therapies is a complex and time-consuming process that typically takes several weeks to complete. The exact timeline for CAR-T manufacturing can vary depending on a variety of factors, including the patient's individual needs and the specific manufacturing protocols used by the therapy's manufacturer, however the average time frame is currently 24 days. Below are the specific timetables for each FDA approved CAR-T manufacturer. CGT Healthcare hopes to eventually accelerate these timelines by days if not weeks.

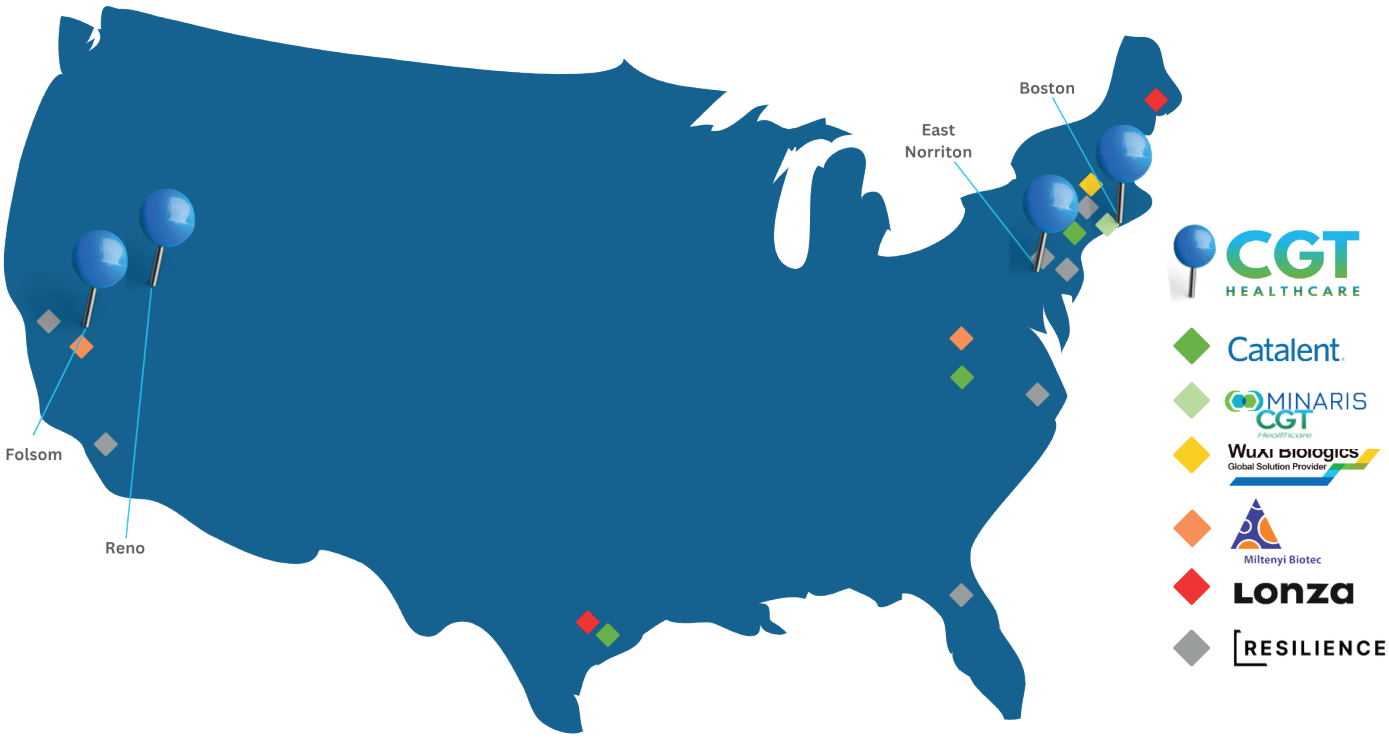
TECARTUS® (brexucabtagene autoleucel)	15 day avg from cell collection to reinfusion
Abecma® (idecabtogene vicleucel)	4 weeks from cell collection to reinfusion
KYMRIAH® (tisagenlecleucel)	3 - 4 weeks from cell collection to reinfusion
CARVYKTI® (ciltacabtagene autoleucel)	4 - 5 weeks from cell collection to reinfusion
Breyanzi® (lisocabtagene maraleucel)	3 - 4 weeks from cell collection to reinfusion

Please note that the manufacturing turnaround times listed are based on best case scenarios and may not always reflect real world manufacturing times. Actual manufacturing times may vary.

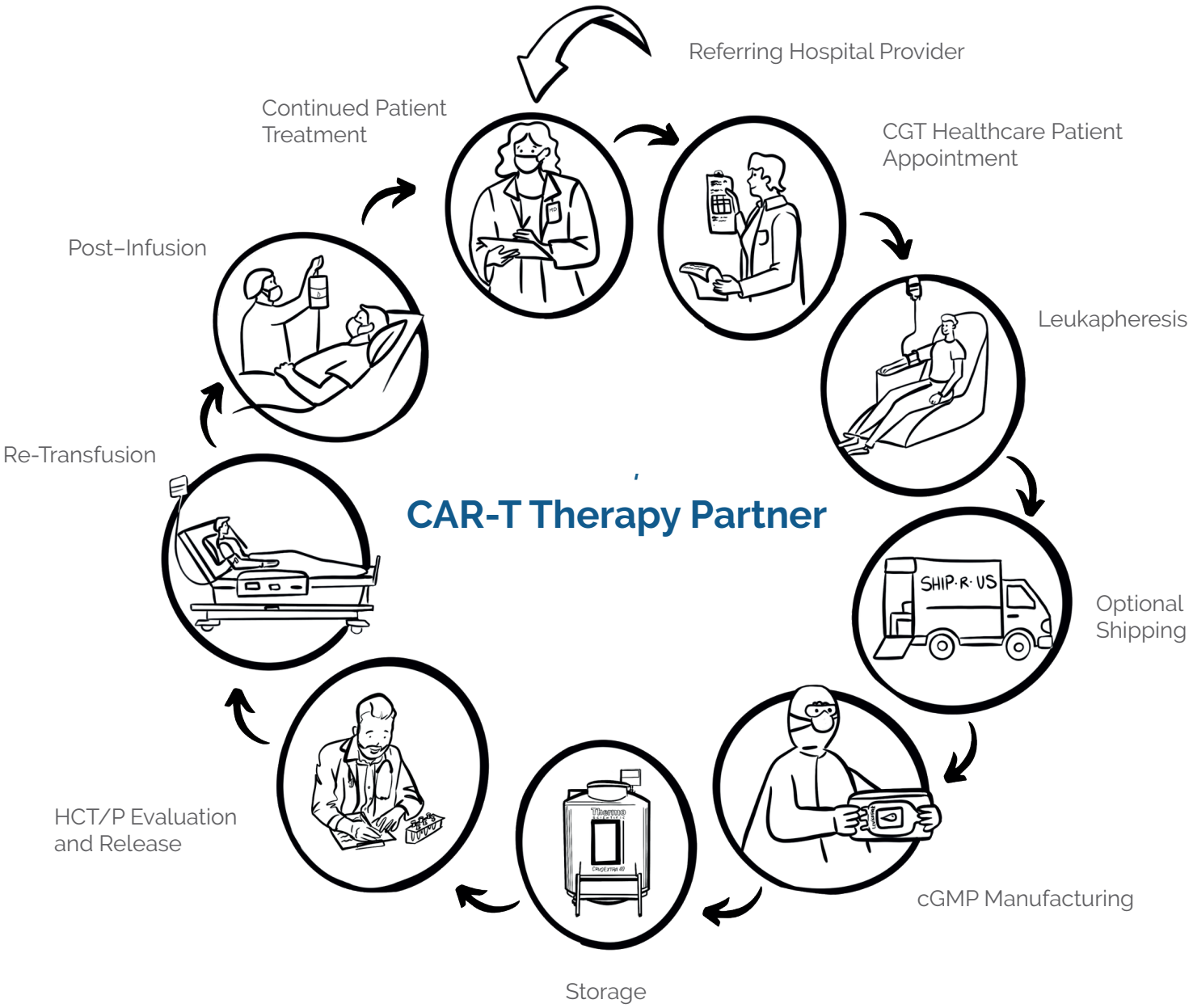
Strategic Locations for Manufacturing Partners

CGT Healthcare has created a strategic network of cell collection clinics with the cell and gene therapy industry in mind. Knowing that many therapeutic developers utilize third party manufacturing or CDMOs, we fulfill clinical collections intended for further manufacturing from our facilities near major US-based CDMO partners. We can also work directly with your CDMO or manufacturing partner to simplify patient collections. Utilizing our coast-to-coast footprint, CGT Healthcare can mitigate risks caused by natural disasters, COVID closures, and other unforeseen circumstances.

Proximity to Major CDMOs



Patient Solutions



CGT Healthcare CAR-T therapy partnership

CGT Healthcare offers patient intake for apheresis collections at all of our CGT Clinics across the nation - providing clinical grade Leukopaks ready for CAR-T therapy manufacturing and re-infusion. We are uniquely positioned to accommodate the needs of your autologous research projects and strategically located in close proximity to major healthcare and biotech spheres to allow for rapid turnaround times from point of collection to use in your research - eliminating the timely logistics in between. CGT Healthcare can also manufacture cells, following hospital SOPs and under hospital's regulatory compliance.

CLOSING THE LOOP IN THE CAR-T PROCESS

CGT Healthcare aims to accelerate the CAR-T therapy process by making apheresis and cell manufacturing more streamlined and accessible - ultimately bringing therapies to more patients, faster. Current manufacturing timelines average 7-21 days, with manufacturer specific guidelines outlined on page 6.

Referring Hospital Provider

Sends patient to CGT Healthcare for CAR-T Apheresis and Manufacturing. Additionally, CGT Healthcare can provide Apheresis on-site if patient is unable to travel

CGT Healthcare Patient Appointment

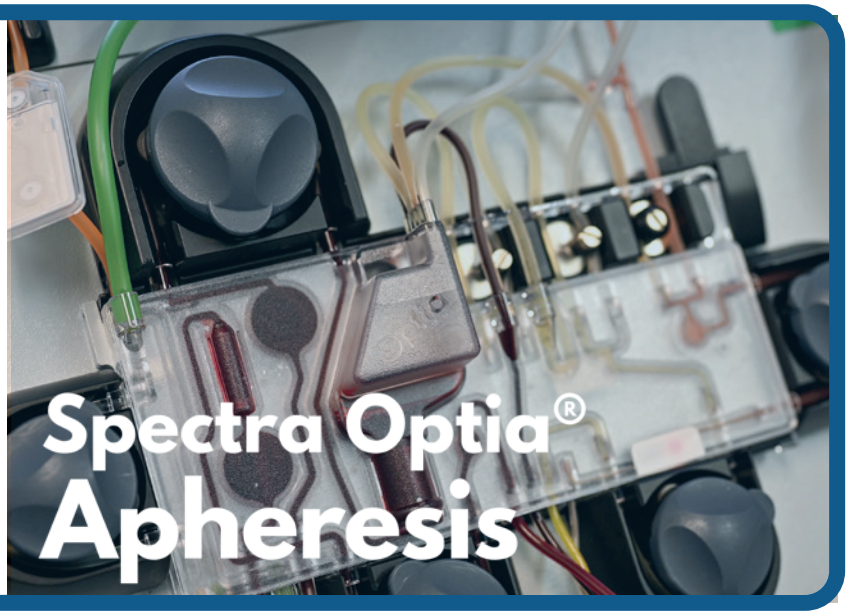
CGT Healthcare physician oversight, release, and review of records

Leukapheresis

CGT Healthcare collects clinical/ therapeutic grade Leukapheresis utilizing state-of-the-art apheresis technology

Leukapheresis

All CGT Healthcare patient collections take place in clean, individual private suites for a safe and comfortable donation experience. Cells are collected on the closed system Terumo Spectra Optia® Apheresis machine. CGT Healthcare employs an RN supervisor at each site, has two Medical Directors on staff and maintains the appropriate FDA registrations, CLIA registrations and State Licensure to collect and ship clinical material intended for further manufacture.



PATIENT SOLUTIONS (CONT.)

Optional Shipping

Product can begin CAR-T therapy at CGT Healthcare location or be shipped to optional pharma manufacturer

cGMP Manufacturing

Cells are genetically modified, expanded, and processed to create CAR-T therapy

Storage

Cells are cryopreserved and stored for patient appointment

Short and Long Term Storage Solutions

CGT Healthcare offers expert cryopreservation and has -80°C and LN2 storage on-site. We use qualified shipping carriers (Cryoport and Quickstat) and have facilities available for long/short term storage.

cGMP Manufacturing

CGT Healthcare houses the CliniMACS Prodigy® on-site, which distills a full scale GMP laboratory into a single unit capable of manufacturing clinical grade products for pharmaceutical, therapeutic devices and autologous production, alleviating the need for hospitals to house and operate cumbersome laboratory equipment. This closed system is approved by the FDA for clinical use and Miltenyi offers multiple isolation kits, or custom technology can be uploaded onto the device as needed for specific projects under research partner's or hospital's regulatory compliance.

CLOSING THE LOOP IN THE CAR-T PROCESS

HCT/P Evaluation and Release

Cells are sent to treatment facility for HCT/P (Human Cell & Tissue Products) evaluation, quality control testing and release

Patient Appointment for Re-Transfusion

Patient re-transfusion takes place within the hospital's healthcare network and under the hospital regulatory guidelines

Post–Infusion

Patient is monitored for Cytokine Release Syndrome and other risk factors

Continued Patient Treatment

Patient returns to referring office for routine monitoring post procedure. Continued care varies based on patients condition, side effects, and response to treatment

REMS

Hospitals are required to have a REMS (Risk Evaluation and Mitigation Strategy) in place in order to provide CAR-T therapy.

Learn more on page 18.

NURSES

Putting CARE in CAR-T Therapy

When a patient is fighting cancer, survivability is the number one priority. CAR-T therapy provides patients with a fighting chance, with success rates of around 30% to 40% for lasting remission[3]. A nurse's top concern is patient care and comfort. CAR-T therapy requires inpatient and outpatient visits during which nurses work closely with other team members and attending physicians to manage treatment and symptoms.

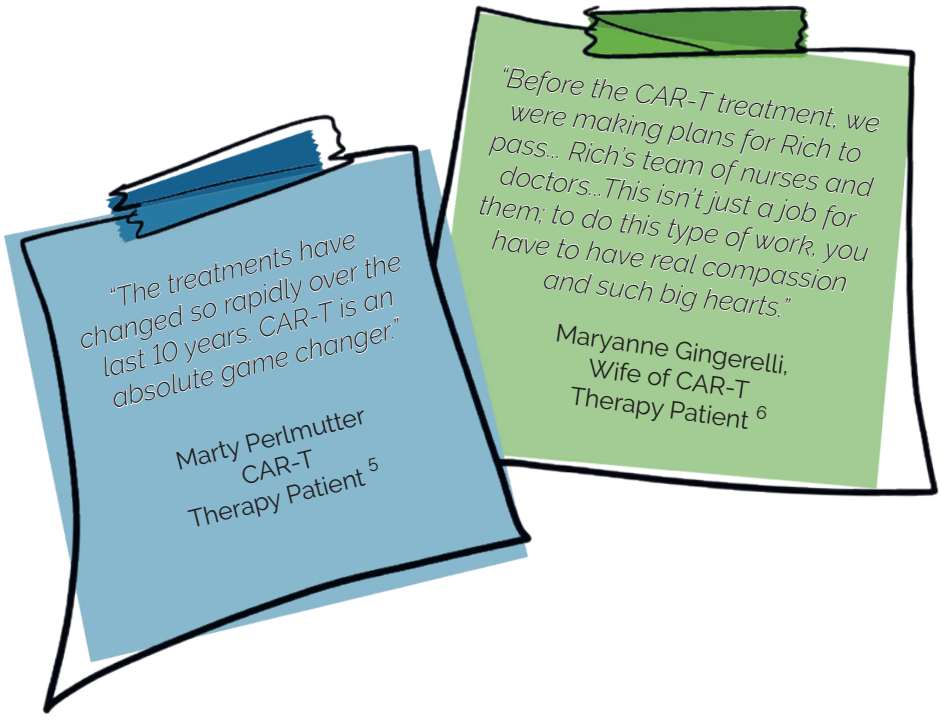
Without the proper care systems in place, patients can experience significant delays in receiving CAR-T treatment. These deferrals have been shown to affect patient outcome, with longer delays in care leading to decreased effectiveness of treatment in some observed cases [4]. This relationship between treatment efficacy and access to treatment further highlights the importance of providing care to patients faster.

THE HUMAN ELEMENT

Nurses play a vital role in helping patients through the process of receiving CAR-T therapy. They provide essential patient education, explaining the treatment process, potential side effects, and what to expect during and after treatment. Nurses also monitor patients closely during treatment and watch for potential complications and help manage the side effects of CAR-T therapy, which can be severe and potentially life-threatening. They may also provide emotional support to patients and their families, helping them cope with the physical and emotional challenges of the treatment process.
In addition to these direct patient care responsibilities, nurses also play an important role in advancing the development and improvement of CAR-T therapy, contributing to the overall knowledge and understanding of how these therapies work and how to optimize their effectiveness and reduce side effects. Overall, nurses are essential members of treatment care team, providing critical patient education, monitoring, and support throughout the treatment process, and contributing to the ongoing improvement of these promising new cancer treatments.

With over 13 years of experience in patient and donor care, CGT Healthcare understands the importance of putting patients first. CGT Healthcare nurses are specialized in providing support in the clinical collection process of CAR-T therapy. Our nurse supervisors are responsible for ensuring high-quality products are delivered to clients, while prioritizing donor safety and compliance with industry standards. In addition, they have the expertise to learn and oversee the apheresis process which differs from traditional blood component exchanges in a hospital setting. With their extensive knowledge and skill set, CGT Healthcare nurses can provide valuable oversight and support in the collection process.

The CGT Healthcare staff and donor/patient relationship is crucial for establishing trust, providing clear communication and ensuring a comfortable and positive experience for all. We work hand-in-hand with nurses and hospital staff to make the CAR-T therapy apheresis process as smooth and stress-free as possible for the patient, so they can focus on healing.



CLINICIANS

Better Patient Outcomes

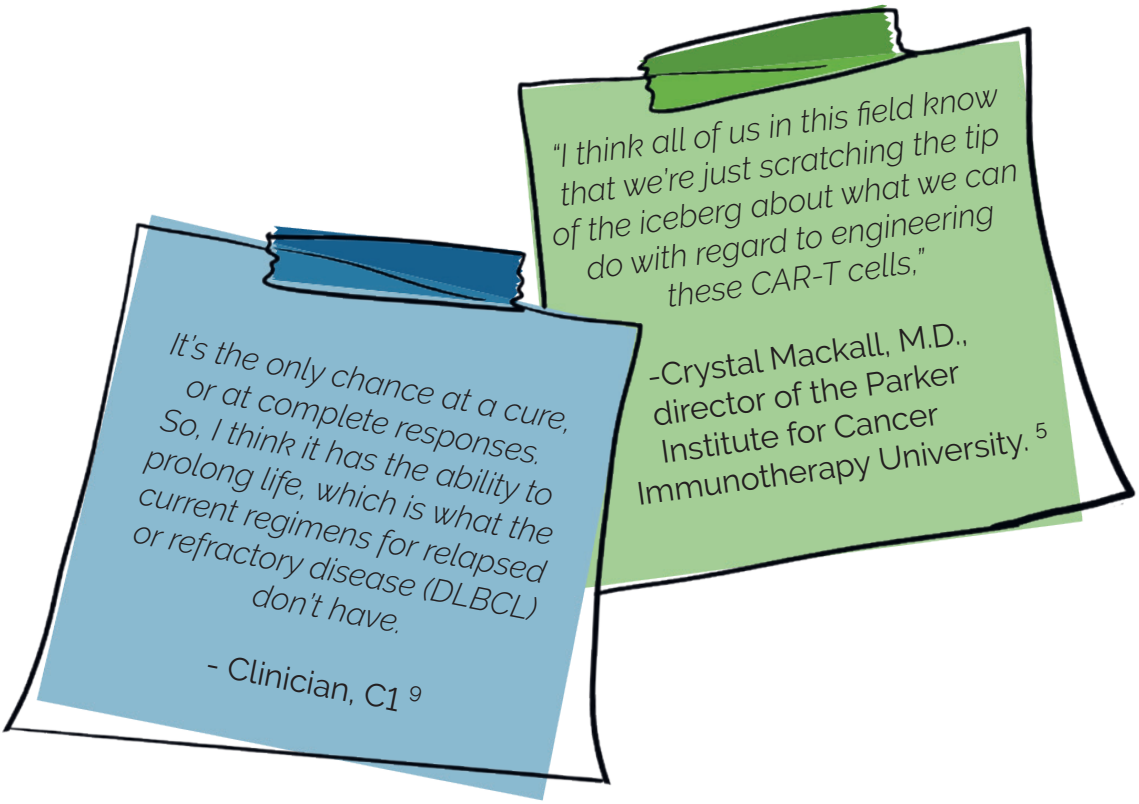
CAR-T therapy offers promising outcomes for patients who did not respond well to previous cancer treatments. The therapy is tailor made to each patient, known as a "living drug", it utilizes the patient's own cells which can remain active in the body long-term, recognizing and attacking cancer if relapse occurs.[7] Because CAR-T therapy success is significant - as high as 30% to 40% for lasting remission with no additional treatment needed [8] - it is expected that the health care system will proactively move to adopt this treatment as a first line of defense against certain cancers.

Increased delays in treatment availability have been shown to have a negative impact on treatment efficacy [4] and wait times will be prolonged if hospital systems are not ready for the influx of patients. It is critical that the resource availability meets the increased patient demand, and that hospital clinicians and team members are trained and prepared. CGT Healthcare can help streamline the process performing some of the integral steps in CAR-T therapy, granting physicians and their teams greater capacity to help more patients in need of treatment.

SIDE EFFECTS AND POST-CARE

As with all cancer treatments, there are side effects to CAR-T therapy that need to be addressed. Because CAR T is relatively new compared to other cancer treatments, the side effects are less understood and need to be further explored to help mitigate these risks over time. More patients undergoing CAR-T therapy will lead to better understanding of the implications and lead to greater survival rates. Below are some of the commonly the known syndromes of CAR-T therapy:

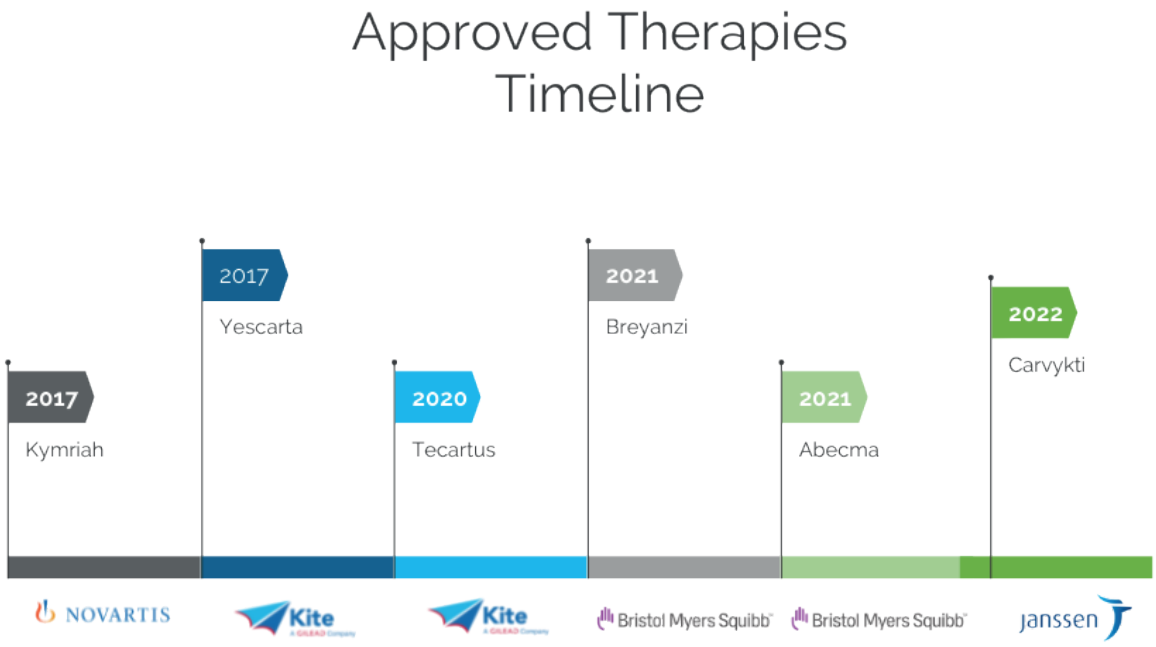
Cytokine Release Syndrome (CRS)	Macrophage Activation Syndrome (MAS)	ICANS
Cytokine Release Syndrome (CRS) is a potentially life-threatening condition in which the immune system produces an excessive amount of cytokines, leading to a range of complications.	Macrophage Activation Syndrome (MAS) is a rare but serious complication of CAR-T therapy in which an overactive immune system response leads to the uncontrolled activation and proliferation of macrophages.	Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) is a rare and potentially life threatening condition in which immune cells attack healthy brain cells, leading to a range of neurological symptoms.



ADMINISTRATORS

Keeping Up, Saving Lives

As CAR-T therapy cancer remission rates continue to show promise, demand for treatment will surely increase, potentially disrupting the current market. Manufacturing will escalate to meet the inevitable influx of patients. As it stands now, companies are not producing CAR-T Cells quickly enough to keep up with the demand. Even when treatment is available, patients are expected to endure long wait times for their cells to be manufactured – typically up to 6 weeks.[11] More hospitals offering this life-saving therapy will ultimately lead to greater survivability for thousands of patients across the country, and more streamlined systems in the years to come.



CAR-T Therapy in Outpatient Setting

CAR-T therapy is typically administered in an inpatient setting, but there is increased interest in providing outpatient options for patients who do not already require inpatient care. [10] Outpatient care would allow far more patients to be seen, thereby decreasing wait times and increasing treatment efficacy. Because this approach is still in its infancy, there are logistical issues surrounding reimbursement in an outpatient setting, but as more hospitals and manufacturers come into the space there will be more guidance on how to code and submit for reimbursement. Figure 4 highlights the current diagnosis codes that are currently approved by The Centers for Medicare and Medicaid Services (CMS) for CAR-T treatment.

CLINICAL HEALTHCARE ICD-10 CODES

Diagnosis Codes with Descriptions
C83.11: Mantle cell lymphoma, lymph nodes of head, face, and neck
C83.12: Mantle cell lymphoma, intrathoracic lymph nodes
C83.13: Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14: Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15: Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16: Mantle cell lymphoma, intrapelvic lymph nodes
C83.17: Mantle cell lymphoma, spleen
C83.18: Mantle cell lymphoma, lymph nodes of multiple sites
C83.19: Mantle cell lymphoma, extranodal and solid organ sites
C83.31: Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32: Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33: Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34: Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35: Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36: Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37: Diffuse large B-cell lymphoma, spleen
C83.38: Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39: Diffuse large B-cell lymphoma, extranodal and solid organ sites
C85.11: Unspecified B-cell lymphoma, lymph nodes of head, face, and neck
C85.12: Unspecified B-cell lymphoma, intrathoracic lymph nodes
C85.13: Unspecified B-cell lymphoma, intra-abdominal lymph nodes
C85.14: Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb
C85.15: Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.16: Unspecified B-cell lymphoma, intrapelvic lymph nodes
C85.17: Unspecified B-cell lymphoma, spleen
C85.18: Unspecified B-cell lymphoma, lymph nodes of multiple sites
C85.19: Unspecified B-cell lymphoma, extranodal and solid organ sites
C85.21: Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face, and neck
C85.22: Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23: Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24: Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25: Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26: Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27: Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28: Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29: Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C85.81: Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face, and neck
C85.82: Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83: Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes
C85.84: Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85: Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C85.86: Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87: Other specified types of non-Hodgkin lymphoma, spleen
C85.88: Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89: Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C91.00: Acute lymphoblastic leukemia, not having achieved remission
C91.02: Acute lymphoblastic leukemia, in relapse

Figure 4. CMS approved CAR-T Therapy ICD-10 diagnosis codes

Please note:

ICD-10 codes C91.00-C91.02 - Acute Lymphoblastic Leukemia diagnosis - are only FDA approved for Kymriah®

ICD-10 codes C83.11-C83.19 - Mantle Cell Lymphoma - are only valid for Tecartus™

For more information on CMS approved diagnosis codes, please visit www.cms.gov/files/document/r10454cp.pdf

BILLING FOR CAR-T THERAPY

REMS (Risk Evaluation and Mitigation Strategies)

The process of preparing to administer CAR-T cell therapy to patients starts with several steps that are collectively known as the REMs (Risk Evaluation and Mitigation Strategies) program. Hospitals must first register with the drug manufacturer and receive certification from the REMs program. Next, healthcare professionals undergo training on the therapy's potential risks and how to manage them. Hospitals must establish protocols for patient selection, treatment, and adverse event management, as well as have specific facilities and equipment in place for patient care. Patient education and informed consent are essential components of the program, and hospitals must report adverse events to the drug manufacturer and regulatory agencies. The REMs program ensures that CAR-T therapy is administered safely and effectively, reducing the risk of serious adverse events and promoting the best possible patient outcomes.

Billing for CAR-T Therapy

Hospital coding for CAR-T therapy identifies the different components of the therapy, including the leukapheresis procedure, the genetic manufacturing of the T-cells, infusion, and any associated monitoring and management services. Proper coding ensures that the hospital can accurately bill for the services provided and receive appropriate reimbursement from insurance providers. In addition to coding, accurate documentation is also crucial to support the services provided and ensure compliance with regulatory requirements.

Disclaimer: The information provided is for informational purposes only and should not be construed as professional advice. The billing and coding procedures for CAR-T therapy can vary depending on factors such as the patient's diagnosis, insurance coverage, and healthcare provider's billing practices. It is recommended to consult with a qualified healthcare professional or billing specialist for guidance on specific billing and coding procedures related to CAR-T therapy. Please also note that healthcare laws and regulations are subject to change, and it is the responsibility of healthcare providers to stay up-to-date on any changes that may affect billing and coding practices.

Applicable HCPCS Codes (Healthcare Common Procedure Coding System)

Company	Generic name	HCPCS Code	Approval
Kymriah	Tisagenlecleucel	Q2042	Up to 600 million viable CAR T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose.
Yescarta	Axicabtagene Ciloleucel	Q2041	Up to 200 Million Autologous Anti-CD19 CAR T-Cells, including leukapheresis and dose preparation procedures, per infusion.
Tecartus	Brexucabtagene Autoleucel	Q2053	Up to 200 million autologous anti-cd19 viable CAR T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose.
Breyanzi	Lisocabtagene Maraleucel	Q2054	Up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose.
Abecma	Idecabtagene Vicleucel	Q2055	Up to 460 million autologous b-cell maturation antigen (bcma) directed CAR T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose.
Carvykti	Ciltacabtagene Autoleucel	C9098	Up to 100 million autologous b-cell maturation antigen (bcma) directed CAR T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose.

Figure 5: Applicable HCPCS codes for CAR-T Therapy billing. *Please note, this is strictly for informational purposes and should not be used as a billing guide. The information provided in this brochure is gathered from various resources, is general in nature, and is subject to change without notice. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies and refer to the Medicare Claims Processing Manual R10454cp for more information on exact billing procedures.
CGT Healthcare is not responsible for any coding issues that may arise.

www.cms.gov/files/document/r10454cp.pdf

BILLING FOR CAR-T THERAPY

Applicable Revenue Codes

Revenue Codes	Description
0871	Cell Collection w/Current Procedural Technology
0872	Specialized Biologic Processing and Storage – Prior to Transport
0873	Storage and Processing after Receipt of Cells from Manufacturer
0874	Infusion of Modified Cells
0891	Special Processed Drugs – FDA Approved Cell Therapy

Figure 6: Applicable Revenue codes for CAR-T Therapy billing

Applicable CPT Codes

CPT Codes	Description
0537T	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
0538T	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
0539T	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
0540T	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous

Figure 7: Applicable Revenue codes for CAR-T Therapy billing

BILLING GUIDELINES FAQ*

When is CAR-T Therapy covered?

Autologous CAR-T therapy treatment is covered by Medicare FFS and Medicare Advantage when two qualifications are met:

- Services are administered at a healthcare facility that is enrolled in the FDA risk evaluation and mitigation strategies (REMS)

- Treatment is used for a medically accepted indication (see figure 4 for ICD-10 approved diagnosis list)

If either of these two criteria are not met, services will not be covered.

What codes should be billed together?

Hospitals may report HCPCS Q2042-C9399 under revenue code 0891 as the covered charge on the outpatient administration claim. The hospital can then report the Category III CPT codes (0537T-0539T) with corresponding revenue codes (0871-0873) on outpatient claims for tracking purposes, and the administration service with 0540T under revenue code 0874 for "modified cell infusion". CPT codes 0537T-0539T are considered bundled charges with the HCPCS Q2042-C9399 revenue codes and will have a line-item rejection but are important for cost data tracking purposes. (R10891NCD.pdf (cms.gov))

What do I do if my claim is denied for medical necessity?

If a claim is denied, the billing and coding department will need to submit a letter of medical necessity. Kymriah provides sample letter templates for Sample Medical Necessity, Sample Formulary Exception and Sample Appeal available upon request. It is recommended you reach out to the appropriate CAR-T therapy drug company for exact guidance on appeals. Please also contact the third-party payers for specific information on their denials, coding, coverage, and payment policies.

Still have questions?

To ensure accurate billing and avoid potential payment issues, it is recommended to contact individual insurance companies for clarification on their specific billing and coding requirements for CAR-T therapy. Insurance companies may have different policies regarding coverage and reimbursement, and it's important to understand their guidelines before proceeding with treatment.

By contacting your insurance company directly, you can obtain clear and accurate information about the billing and coding process.

*Please note, this is strictly for informational purposes and should not be used as a billing guide. The information provided in this brochure is gathered from various resources, is general in nature, and is subject to change without notice. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies and refer to the Medicare Claims Processing Manual R10454cp for more information on exact billing procedures. CGT Healthcare is not responsible for any coding issues that may arise.

www.cms.gov/files/document/r10454cp.pdf

OUR TEAM

CGT Healthcare is a leading global provider of human primary cells, stem cells, bone marrow, cord blood, peripheral blood, and disease-state products. Our products are used for research and development, clinical trials, and commercial production of cell and gene therapies (allogeneic or autologous) by academic, biotech, diagnostic, pharmaceutical and contract research organizations (CRO's).

CGT Healthcare is registered with the U.S. Food and Drug Administration (FDA) and has over a dozen global distribution partners and strategically located CGT Clinics in the United States. It has been ranked by Inc. 500 as one of the fastest growing companies in the U.S. Learn more at CGTHealthcare.com.

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FAQ

How effective is CAR-T therapy in treating cancer?
CAR-T therapy has shown promising results in treating certain types of blood cancers, with some patients experiencing complete remission. However, not all patients respond to CAR-T therapy, and more research is needed to determine its effectiveness in treating other types of cancer.

What is the role of the hospital in the CAR-T therapy process?
Hospitals play a critical role in the CAR-T therapy process, from collecting and modifying the patient's T cells to monitoring the patient for potential side effects and providing supportive care as needed. Hospitals also work closely with insurance providers and patients to ensure that the treatment is covered and that the patient's care is coordinated throughout the process.

What is the future of CAR-T therapy?
As research on CAR-T therapy continues, it is likely that more hospitals will begin offering this treatment for a wider range of cancer types. In addition, advances in technology and genetic engineering may make CAR-T therapy more targeted and effective, potentially leading to even better outcomes for patients with cancer.

Citations

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