

Bringing CAR T-Cell Therapies to Community Oncology

In recent years, chimeric antigen receptor T-cell therapy (CAR T) has emerged as an important treatment, offering the promise of disease-free survival to patients with relapsed/refractory hematologic cancers. By attaching a chimeric antigen receptor to patients' own T cells and then expanding these cells, CAR T-cell therapy creates a personalized immune therapy where the patient's own cells are able to target cancer cells. The goal of a cancer cure has yet to be reached, but impressive response rates and progression-free periods have been achieved with CAR T-cell therapy in clinical trials, establishing CAR T as a new standard of care for certain cancers.

Since the FDA approved the first two CAR T-cell therapies (Kymriah and Yescarta) in 2017 to treat acute lymphocytic leukemia (ALL) and non-Hodgkins lymphoma (NHL), research into new CAR T-cell products for cancer has exploded. According to the Center for International Blood and Marrow Transplant Research, which collects data on patients receiving CAR T-cell therapy, more than 2,000 individuals received CAR T-cell infusions between 2016 and 2019.¹ At the 2020 meeting of the American Society of Clinical Oncologists (ASCO), it was reported that more than 600 clinical trials involving CAR T-cell therapies were in progress globally, and the U.S. Food and Drug Administration (FDA) was "expected to approve between 10 to 20 gene therapy products per year by 2025."²

Currently, there is one CAR T-cell product approved by the FDA for the treatment of relapsed/refractory multiple myeloma. In a phase two study, the bb2121 CAR-T therapy known as idecabtagene vicleucel, or ide-cel, demonstrated a 73% response rate with a median progression-free survival (PFS) of 8.8 months. Ide-cel was the first cell-based gene therapy approved for multiple myeloma.³

Additionally, ciltacabtagene autoleucel, or cilta-cel, is under priority review for relapsed/refractory multiple myeloma based on an early-phase clinical trial that yielded an overall response rate of 97% with a stringent complete response (CR) in 67% of the evaluable patients.⁴

There are more than 100 cancer centers authorized to administer CAR T-cell therapy in the U.S.⁵ Historically, large research hospitals with well-established bone marrow transplant units have been the first to begin offering new immune effector cell treatments, with community oncologists supplying referrals.⁶ The push to expand access to these life-saving therapies could place community cancer centers at the new forefront of CAR T-cell research. To be able to offer such services, however, community providers must first overcome several challenges, including resolving problems with complex care coordination, safety issues, and high costs.

Patient Eligibility and Selection

Treating patients with autologous CAR T-cell therapy is a multi-stage process, comprised of patient eligibility and selection; leukapheresis (cell collection); CAR T-cell processing and expansion and potential bridge therapy; lymphodepletion and CAR T infusion; and monitoring and follow-up care (see diagram, page 2).

To help providers make patient selection decisions in a rapidly expanding and changing field of treatments, cancer centers should form a multidisciplinary committee. In a 2018 American Society for Blood and Marrow Transplantation survey of cancer centers authorized to administer CAR T-cell therapy, 60% of respondents reported using a multidisciplinary team to analyze a patient's clinical data prior to approval.⁸ Interdisciplinary committees should include a pharmacist and a medical business executive familiar with

the costs and benefits associated with immune effector cell therapy.⁸

Selecting eligible patients involves clinical evaluation, financial pre-authorization and patient education.

1. The clinical evaluation requires providers to assess a patient's disease type, tumor burden, previous lines of therapy, and risk factors for severe adverse reactions. Due to the high potential for cytokine release syndrome following CAR T infusion, a patient must meet reasonable renal, cardiac, and pulmonary function requirements before approval.⁷
2. Before a patient can be considered for CAR T-cell therapy, a financial navigator or other designated staff member must obtain insurance pre-authorization. As real-world data on the positive outcomes of CAR T-cell therapy grows, more insurance companies are covering new immune effector cell treatments. However, the process still takes time.
3. Designated cancer team members must educate both patients and caregivers about the risks, benefits, and processes of CAR T-cell therapy and gain informed consent. Some oncology nurses are advocating for the creation of a cellular therapy coordinator (CTC) role to guide patients through the entire process and manage communication among all stakeholders, including CAR T product manufacturers, physicians, pharmacists, radiologists, apheresis specialists, insurance companies, and patients.⁹ The CTC would be responsible for tracking outcome and toxicity data and reporting it to the Center for International Blood and

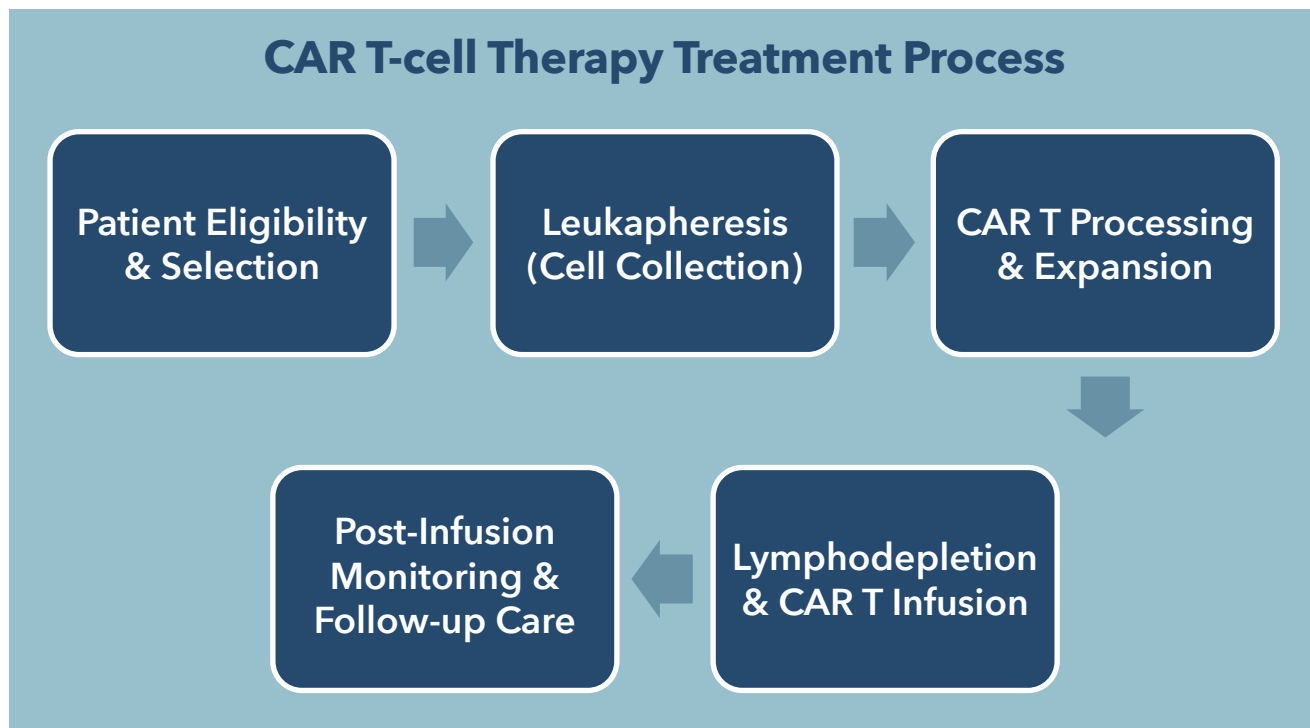
Marrow Transplantation Research, which maintains a global database on patient experience with CAR T-cell therapies.⁹

4. Social work services should be incorporated early in the process of patient evaluation and education to gauge the patients' and caregivers' ability to undertake the CAR T process and to provide emotional, psychological, and financial support as needed.

Patient Treatment

The next step for eligible patients is cell collection. Leukapheresis requires a temporary dialysis catheter or central line, but it can be performed in an outpatient community setting.¹⁰ The harvested T cells are sent to an FDA-approved facility for processing, which typically takes two to four weeks.¹⁰ During this time, there is a risk for disease progression that could preclude the patient from receiving CAR T. Consequently, cancer centers should be prepared to offer bridge therapy, frequently with cyclophosphamide or high-dose steroids,¹⁰ to help the patient maintain eligibility for treatment. However, not all patients may benefit from bridge therapy, so it is important to select the appropriate patients.

Throughout CAR T-cell treatment (from apheresis to post-infusion), patients and their caregivers are required to stay close to their treatment facility (usually within 30 miles).¹¹ For patients living remotely, this can mean additional costs incurred for travel and lodging, which can create a barrier to access. There are some resources available to help cover these costs, such as the travel assistance program offered by the Leukemia and Lymphoma Society as well as travel and lodging coverage provided by CAR T-cell companies.¹²



However, when community cancer centers can administer CAR T-cell therapies closer to patients' homes, the burden and cost of travel can be alleviated. In order to ensure that caretakers can take care of the patient for the first 30 days post-infusion, many centers perform a caregiver assessment, particularly if the patient is treated in the outpatient setting.

Just prior to CAR T-cell infusion, the patient undergoes lymphodepletion commonly with chemotherapy regimens, which can be administered in the outpatient setting, to prepare the body to accept the modified T cells. The CAR-T infusion typically takes place in an inpatient setting to maintain adequate patient supervision and provide treatment in case of an adverse reaction, but it can be infused outpatient as well, depending on the onset of toxicities of the specific product. Current best practices recommend monitoring patients daily for the first seven days after an infusion, and weekly for at least one month thereafter, although many patients may require more frequent monitoring.¹¹

Toxicity and Adverse Event Management

Safety during and post-infusion is the driving factor behind the FDA's Risk Evaluation and Mitigation Strategy (REMS) requirement for the administration of all CAR T products. The most common adverse events associated with infusion include cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). According to analyses of clinical studies from 2015 to 2020, roughly 80% of patients receiving CAR T-cell therapy developed CRS, and approximately 10% experienced ICANS.¹³

Cytokine release syndrome frequently occurs following T-cell infusion because macrophages are stimulated to overproduce cytokines, particularly interleukin-6.¹⁴ Tocilizumab, which blocks the action of IL-6, was approved by the FDA in 2017 for the treatment of CRS.¹⁴ In 2019, the American Society for Transplantation and Cellular Therapy (ASTCT) issued a streamlined grading system for CRS, wherein the administration of tocilizumab is recommended as early as stage 2.¹⁵ According to Schubert et. al., "with early and aggressive management, even high-grade CRS is reversible."¹⁵ Now, fewer patients have to be escalated to intensive care for the treatment of CRS.¹⁵

Observing patients for the development of ICANS post-infusion is also critical, although ICANS tends to occur less frequently than CRS and does not require the administration of tocilizumab (unless the patient presents with concurrent CRS).¹⁵ The ASTCT has developed a grading system for ICANS using the immune-effector cell-associated encephalopathy (ICE) assessment tool in addition to measurements of seizure, motor activity, consciousness, and intracranial pressure.¹⁵ Low-grade ICANS is typically treated with steroids and supportive care, with some practices opting to administer seizure prophylaxis.¹⁵ If anti-seizure drugs are prescribed, patients must be closely monitored for drug-induced decreases in level of consciousness, which could obscure the accurate assessment of cognitive status.¹⁵

According to current research, CAR T-cell infusions may be administered in an outpatient setting for select patients deemed low-risk for complications.¹⁶ All clinical staff involved in cellular therapy administration must be trained to recognize early signs of CRS and ICANS and have immediate access to the CRS-reversal agent tocilizumab, as well as oxygen and other emergency equipment.¹⁶ In the outpatient setting, it is even more important that staff, patients, and caregivers are educated about the symptoms of SAEs and their appropriate response.

In July 2020, the ACCC Immuno-Oncology Institute began offering immuno-oncology wallet cards¹⁷ to cancer programs and practices that provide CAR T-cell therapy to their patients. These cards help raise awareness among patients, primary care doctors, and emergency room personnel about CAR T-cell related adverse events. Wallet cards describing the signs and symptoms of severe adverse reactions and explaining when to call the doctor are now required by the FDA as part of the risk evaluation and mitigation strategies for all CAR T products.¹⁸

Another strategy for facilitating post-infusion patient care in the outpatient setting was developed by Vanderbilt Medical Center in Tennessee. At Vanderbilt, immuno-oncology providers use advanced telehealth services to track patient vital signs and monitor low-risk patients for signs and symptoms of adverse reactions in the weeks following infusion.¹⁹

Financial Toxicity

Cost and reimbursement for cellular therapy poses another barrier to prospective patients and their providers. According to *The American Society of Clinical Oncology (ASCO)*, the cost for the CAR T product alone averages more than \$300,000 for a single infusion,²⁰ which does not include accompanying services and follow-up care.²¹ Patients with private insurance may have large co-pays for ancillary procedures such as lymphodepletion before therapy and monitoring and treatment of any adverse effects following infusion. Although non-profit organizations and some pharmaceutical companies offer financial assistance to eligible patients, financial toxicity remains a problem, making early consultation with financial navigators an absolute necessity.

Providers also bear a financial risk when offering cellular therapy. Reimbursement for CAR T-cell therapy is typically less than the costs incurred for providing it, although strides have been made to ease this financial burden. When it was first approved by the FDA in 2017, CAR T therapy was included in the pre-existing diagnosis-related group for autologous bone marrow transplantation, DRG 016, with an average reimbursement rate of \$43,094.²² In 2021, the Centers for Medicare & Medicaid Services (CMS) announced the establishment of a new diagnosis-related group—MS-DRG018—for the reimbursement of CAR T-cell therapy, with payment for this group set at \$239,929.²² As noted by ASCO, however, this amount is less than the cost of the CAR T product itself, which typically averages more than \$300,000

per infusion.²² Nevertheless, this represents an increase from initial reimbursement rates for CAR T therapy. It is worth noting that some therapies have a better reimbursement rate when infused in the outpatient setting if they can be safely administered outpatient.

There is still much work to be done to ensure that cancer centers can afford to offer CAR T-cell therapy to the patients who need it. For example, the MS-DRG018 reimbursement rate does not cover the added expense of drugs such as tocilizumab, which is used to treat cytokine release syndrome and costs an average of \$2,000 per dose.²³

In an attempt to manage financial risk, some payers are exploring alternative payment plans such as milestone-based contracts (MBCs) and outcomes-based agreements (OBAs).²⁴ According to Kansagra, et. al., MBCs are designed to reimburse providers at the conclusion of each stage of the care delivery process (from apheresis to bridge therapy to lymphodepletion and infusion, etc.).²⁴ Kansagra, et. al. note that “the use of milestones acknowledges that a patient may progress to some but not all of the phases of care . . . and allow[s] for payment to the provider for those services already provided while retaining the rest of the funds if the full treatment episode is not completed.”²⁴

Novartis is offering an OBA payment program for the use of Kymriah in pediatric ALL.²⁴ In the case of the Novartis OBA for the use of Tisa-cel in the treatment of pediatric patients with B-cell ALL, insurance companies do not have to pay if the patient does not achieve complete remission by the 35th day post-infusion.²⁴ Tying the payment mechanism to the evaluation of patient outcomes may create problematic delays for billing departments, but it removes the risk burden from providers and streamlines the approval process.

As CAR T therapy continues to be adopted as standard care, real-world data will reflect its true value, increasing payer confidence and expanding insurance coverage and reimbursement rates. According to researchers using data from Tufts Medical Center’s Cost-Effectiveness Analysis Registry and the Institute for Clinical and Economic Review, “CAR T provided 5.03 (95% CI: 3.88–6.18) more incremental quality-adjusted life-years than the average pharmaceutical intervention, and 4.61 (95% CI: 1.67–7.56) more than the average nonpharmaceutical intervention, while retaining similar cost-effectiveness.”²⁵

Roadmap to CAR T Certification

For community cancer centers wishing to add CAR T-cell products to their formularies, the risk evaluation mitigation strategies required for approved cellular therapies can serve as a guide for developing necessary protocols and resources for toxicity management. Centers offering CAR T for the treatment of relapsed/refractory multiple myeloma, for example, must demonstrate that they have immediate access to two doses of tocilizumab per patient for the reversal of acute CRS, and they must train all staff to recognize and manage adverse reactions.¹⁸ In addition, cancer centers must designate an authorized representative (AR) to undergo

initial REMS training, keep records of staff training and other required processes, and report any SAEs to the appropriate authorities.¹⁸

To become a certified CAR T infusion center, oncology providers should consider applying for accreditation from the Foundation for Accreditation of Cellular Therapy (FACT), although FACT accreditation is not required by all CAR T pharmaceutical companies.²⁶ FACT provides detailed checklists to help cancer centers develop the standardized protocols and pathways they need to safely administer CAR T-cell therapy. Among the clinical program staff required for a program or practice to receive FACT accreditation are a clinical program director, a quality manager, and at least one other cellular therapy specialist.²⁶ The program must also follow strict guidelines for maintaining chain of custody of autologous CAR T products and possess adequate clinical space and staff equipped to provide post-infusion inpatient care.²⁶

Although the path to CAR T certification may be challenging, resources and momentum exist among community cancer centers to offer these life-saving treatments to many patients currently without access.

The Future of CAR T-Cell Therapy

If the number of ongoing clinical trials and new CAR T-cell products in the pipeline are any indication, the future of CAR T-cell therapy is bright indeed. Complete response rates and progression-free survival for heavily pre-treated patients with relapsed/refractory cancers are encouraging researchers to explore ways to make CAR T cells even more effective.

Scientists are investigating factors that may contribute to immune escape such as antigen loss, and they are developing strategies to address them. One such strategy is developing CAR T-cell therapies that target multiple antigens at once.²⁷ While CAR T drugs for ALL and NHL target the CD-19 antigen, and drugs for multiple myeloma target the BCMA antigen, new drugs are being developed that target antigens such as CD138 and GPRC5D.²⁷ Another approach involves administering oral g-secretase inhibitors (GSI) to help prevent BCMA antigen loss and improve CAR T-cell efficacy.²⁷

The time involved in the apheresis and manufacture of CAR T-cell therapies from a patient’s autologous sample has prompted some scientists to pursue “off-the-shelf”, or allogenic, CAR Ts.²⁸ Such cells would come from allogeneic donors and be kept in temperature-controlled settings for use as soon as they are needed.²⁸ Studies to measure efficacy and safety—including strategies to combat/prevent graft-vs-host disease—are already underway.²⁸

Thus far, CAR T-cell therapy has proven effective in treating hematologic cancers due to the location of malignant cells in blood and bone marrow, where T cells normally circulate. The next frontier is the development of CAR T cells capable of infiltrating solid tumors.²⁹

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