

# CAR T-Cell Therapy in Action: Successful Examples in Outpatient Settings

## *Bringing CAR T-Cell Therapy to Community Oncology*

### Introduction

Chimeric antigen receptor (CAR) T-cell therapy has transformed the landscape of hematologic malignancies over the past decade. The use of CAR T-cell therapy continues to grow as clinicians across the continuum of care become better acquainted with these advanced therapies. In the community care setting, early and accurate patient identification for CAR T-cell therapy is critical for appropriate and timely treatment.<sup>1</sup> Often, patients with advanced hematologic cancers are considered for/become aware of CAR T-cell therapy after the optimal treatment window has closed. Additionally, there are significant financial, logistical, and educational barriers that patients and their caregivers face to accessing this potentially life-saving immunotherapy.<sup>2</sup>

As the majority of patients with cancer in the United States undergo treatment in community healthcare settings, there exists a potential risk of missing crucial opportunities for novel therapies. Community oncologists hold significant potential in recognizing and referring eligible patients to accredited treatment centers for CAR T-cell therapy. Therefore, ensuring robust provider education and implementing effective referral

practices within the community care setting becomes crucial for enhancing accessibility to CAR T-cell therapies within local communities.<sup>3</sup>

Beyond this, some community cancer centers have moved to establish their own outpatient CAR T-cell therapy programs. Outpatient CAR T-cell therapy administration may improve patient satisfaction, increase reimbursement rates, and expand accessibility, but it is not an easy feat.<sup>2</sup> Successful implementation of an outpatient program requires a cancer center to meet infrastructural needs, have adequate staffing, provide comprehensive education and training, establish reliable patient monitoring protocols, and have processes in place to triage patients and navigate issues.

As part of its initiative **Bringing CAR T-Cell Therapies to Community Oncology**, the Association of Cancer Care Centers (ACCC) shares a look at cancer programs that have been successful in establishing outpatient CAR T-cell therapy services or are in various stages of bringing CAR T-cell therapy to ambulatory settings.

### City of Hope National Medical Center

City of Hope National Medical Center in Duarte, California, is a National Cancer Institute (NCI)-designated comprehensive cancer center and a founding member of the National Comprehensive Cancer Network. Comprised of 1 main hospital and several community sites across the Los Angeles area, City of Hope serves a largely urban population and has treated nearly 500 patients with CAR T-cell therapy between 2020 and 2023. In May 2022, City of Hope administered its first CAR T-cell infusion in the outpatient setting. Since then, the practice has fully transitioned its CAR T-cell therapy process to the outpatient setting with great success.

To implement this shift, detailed procedures were established to guide clinicians along each step of the CAR T-cell therapy process (similar to starting an inpatient program), but with extra considerations for outpatient use. To facilitate appropriate selection of outpatient candidates, City of Hope created standard operating procedures delineating strict criteria of patient and caregiver candidacy. One of the main criteria is patient proximity to the institution, measured in time instead of distance, as traffic in the surrounding area can easily turn a 15-mile distance from 20 minutes of travel time into 3 hours. City of Hope requires patients to stay within a 30-minute drive of the institution for the first 14 days post infusion. For the remaining 28 days, patients may reside within a 2-hour drive. In 2022, City of Hope opened the Judy & Bernard Briskin Hope Village on campus, which is a 147-room hotel that can accommodate patients who are not within a 30-minute drive.

#### TIP

Opening a hotel or sponsoring a local hotel stay can be an effective method for addressing geographical barriers to CAR T-cell therapy, provided the institution has the resources to invest in such measures.

A reliable caregiver is another nonnegotiable condition for outpatient treatment at City of Hope. Caregivers, who may be family members, friends, privately paid professionals, or other individuals, play an integral role in a patient's therapy, particularly in outpatient CAR T-cell therapy programs. In order to receive CAR T-cell therapy, patients must have someone who is able to spend 24 hours per day with them to monitor vitals and accompany them to the cancer center as needed.

#### Appropriate caregivers should be<sup>5</sup>:

- At least 18 years of age and able to drive
- Able to stay with patient 24 hours a day during outpatient stages
- Able to transport patient to appointments and participate in care team meetings
- Able to manage patient medication and administration
- Responsible for practicing safe, off-site chemotherapy precautions
- Responsible for cleaning and cooking during care stages
- Responsible for knowing when to call and who to call on the medical team for emergencies

Finally, financial screening must be conducted to ascertain if outpatient administration would be covered by the patient's insurance. At City of Hope, a team of financial coordinators works to submit each case to the insurance provider after the patient is deemed eligible for outpatient treatment from clinical, logistical, and psychosocial perspectives. If the patient needs to be admitted at any time, another authorization is submitted to the insurance provider to convert the patient to an inpatient stay. In City of Hope's experience, most insurance providers are generally compliant and do not pose issues if a patient's circumstance changes from outpatient to inpatient.

Aside from maintaining strict criteria to select the most appropriate candidates, City of Hope's efforts are also heavily concentrated on post-infusion monitoring. All members of the care team, including nurse practitioners who interact most often with patients, are rigorously trained to recognize signs and symptoms of cytokine release syndrome (CRS) and other therapy-related toxicities and guidelines are included in all standard operating procedures. Patients are required to present daily for the first 14 to 21 days post-infusion for evaluation by an advanced practice provider or physician. They also receive intravenous hydration for the first 14 days after infusion.

 **TIP**

City of Hope maintains a 24/7 nursing triage line in which nurses have a specific set of questions to ask patients recently treated with CAR T-cell therapy.

If an answer triggers an admission, then the patient is asked to present to the treatment and evaluation center, from which they could be admitted if there is a significant concern for CAR T-cell toxicities. One of the inpatient units has a reserved bed to ensure there is always an available bed should a patient need urgent admission. Murali Janakiram, MD, MS, a hematologist oncologist at City of Hope, notes that having the capacity to admit patients as soon as side effects are recognized is critical to the success of an outpatient program.

One of the ongoing challenges with CAR T-cell therapy across all practice settings is the development of a strong referral network to identify eligible patients. Despite the success of its current program, Dr Janakiram estimates that City of Hope is treating less than a quarter of patients in the area who may be eligible to receive therapy. To capture more referrals, City of Hope uses its email network for outreach to other clinicians to share the benefits of outpatient CAR T-cell therapy at its center. Educating community physicians about the data behind therapy and the feasibility of outpatient administration is the first step toward establishing a strong referral network. But ultimately, it is the patient success story—one who is successfully treated in the outpatient setting and returns to the community provider—that will serve as the most compelling driver for referrals.

**Astera Cancer Care**

Astera Cancer Care is a physician-owned, multispecialty, community oncology practice that provides comprehensive cancer care at its 8 medical oncology, 8 radiation oncology, and 2 breast surgery sites throughout the New Jersey and Greater Philadelphia areas. Astera Cancer Care prides itself on providing innovative care and disrupting the status quo in the community oncology setting. Its leadership believes that the current model of healthcare precludes equitable access to cutting-edge cancer care. As one of the first community practices in the country to offer CAR T-cell therapy, Astera Cancer Care had to overcome unique barriers to administer this therapy without an affiliated hospital.

 **TIP**

Edward J. Licitra, MD, PhD, a medical hematologist oncologist, and cofounder and CEO of Astera Cancer Care, emphasizes that the first step to implementing outpatient CAR T-cell therapy is to have a local champion who will serve as the resident expert.

This individual, typically a hematologist oncologist, needs to take ownership of the CAR T-cell therapy program and form a task force composed of ancillary staff who will take on other leadership roles. It is important to have an interdisciplinary workforce, including nurses, advanced practice providers, pharmacists, lab personnel, financial navigators, social workers, and more, to fully address the clinical, financial, and psychosocial complexities of CAR T-cell therapy.

 **TIP**

The second—and likely most challenging—step for a community practice to implement CAR T-cell therapy is finding a partner hospital to collaborate with in the event of admission.

Large academic institutions that use CAR T-cell therapy typically start with administration in the inpatient setting and eventually shift their focus to outpatient use. At Astera Cancer Care, however, the rate-limiting step was not outpatient operationalization, rather it was the establishment of inpatient support services. It was, in a sense, working backwards.

Hospitals must devote extensive training and resources to support admissions for CAR T-cell toxicity and it is no small request to ask a local hospital to take on these complicated cases. Finding an unaffiliated partner hospital that is willing to collaborate with a community-based practice in providing innovative therapies ultimately depends on hospital leadership. Not only must a partner hospital want to raise the level of its organization, but it must also understand that for everyone—community practices, local hospitals, and patients—to survive in the current healthcare climate, collaboration is necessary. Many patients cannot access large academic institutions, and community practices may be the only option for them to receive CAR T-cell therapy. Furthermore, from an economic standpoint, community practices and local hospitals that do not offer novel treatments risk losing patients to larger centers.

Thus, if community practices and local hospitals cannot work together to support such therapies, then patients suffer clinically, and practices suffer financially.

Partnering with a local hospital requires an extensive amount of preparation from the community practice, especially when, as Dr Licitra recommends, the practice is looking for hospitals that do not already have their own bone marrow transplant or CAR T-cell therapy programs, because those hospitals will be less interested in collaborating with an unaffiliated community practice. However, this means that the chosen partner hospital is essentially starting from scratch with CAR T-cell therapy.

In 2018, Astera Cancer Care partnered with Saint Peter's University Hospital in New Brunswick, NJ, to launch some of the first CAR T-cell therapy clinical trials. To prepare the partner hospital, Astera Cancer Care took on the responsibilities of developing policies and procedures for patient triage and toxicity management and training the inpatient staff to support CAR T-cell therapy-related admissions. It provided educational cards to the inpatient providers detailing how to deal with various clinical scenarios. It also preregistered each CAR T-cell therapy patient in the partner hospital's electronic medical record (EMR) and optimized the EMR to flag the patient as a CAR T-cell therapy patient for more efficient care.

In addition to spearheading inpatient operations, Astera Cancer Care is working with New Jersey payers to create novel reimbursement models for CAR T-cell therapy delivery that encompass all aspects of care in an "episode of care" payment structure. Essentially, Astera Cancer Care works with payers to determine a single price that is paid for the entire episode of care, from patient identification through CAR T-cell therapy preparation and infusion, and up to 90 days post infusion, including coverage of inpatient admission to the partner hospital. Once this amount is determined, the burden falls upon the practice to appropriately manage the patient within the bundled payment, encouraging providers to focus on quality of care, as opposed to quantity in a traditional pay-per-service approach.

The "episode of care" payment amount may differ based on the specific CAR T-cell therapy product and indication. Astera Cancer Care believes that the "episode of care" payment model can help to reform cancer care reimbursement by prioritizing value-based care, controlling costs, and increasing quality outcomes.

### St Luke's Cancer Institute

St Luke's Cancer Institute in Boise, Idaho, is the flagship hospital of St Luke's Health System, a not-for-profit system that serves as the largest healthcare provider in the state of Idaho. St Luke's Cancer Institute has been administering inpatient CAR T-cell therapy since June 2022 and is now preparing to transition certain cases to the outpatient setting in hopes of expanding access to patient care, reducing costs for both patients and the organization, and potentially increasing reimbursement. Outpatient administration will be determined on a case-by-case basis and will occur in the ambulatory infusion clinic on the main hospital campus.

When St Luke's Cancer Institute first started integrating CAR T-cell therapy into its practice, one of the largest operational barriers was obtaining authorizations and single-case reimbursement rates in a timely fashion so that patients would not be delayed for therapy. The institution found that many local payers were not familiar with CAR T-cell therapies and did not have clear authorization pathways in place, requiring the institution to spend a great deal of time educating payers about CAR T-cell therapy processes. Furthermore, variations in the authorization process across different medical plans—even ones within the same network—or fragmented authorizations for a single therapy—in which the institution must obtain several different authorizations at multiple times for a single planned therapy—contributed to long turnaround times.

Because St Luke's Cancer Institute is not part of any national transplant networks, single-case agreements still need to be submitted for national payers such as Cigna, Blue Cross, and United Healthcare. However, what has helped St Luke's Cancer Institute overcome some of these reimbursement delays is implementation of a negotiated CAR T-cell therapy inclusion to existing reimbursement contracts with payers (primarily with local payers in the state of Idaho), so that the institution does not have to submit single-case agreements for each patient. Thus far, these contracts have only been established for inpatient administration, but the eventual goal is to have contracts in place for outpatient administration, as well. The contracts allow for a set amount to be reimbursed for each patient based on the specific insurance.

Depending on the payer, some contracts may include leukapheresis and preparation for CAR T-cell therapy, while others may cover only the cost of therapy itself. To determine

appropriate reimbursement amounts, St Luke's Cancer Institute partners with various internal teams (eg, legal, finance, pharmacy) to establish rates.

### TIP

To help streamline the reimbursement process, St Luke's Cancer Institute employs patient financial advocates who are responsible for submitting prior authorizations and necessary documentation.

Before sending the documentation to the payer, the financial advocate must send the information to the in-house medical coding team to check if there is any missing documentation on the back end. Incorrect coding can lead to discrepancies in reimbursement, and it is important to catch errors before documentation is sent to the payer. The CAR T-cell therapy team at St Luke's Cancer Institute also holds bimonthly meetings to review all CAR T-cell therapy cases, and any reimbursement discrepancies are discussed at that time.

Reimbursement issues aside, another significant hurdle for St Luke's Cancer Institute was acquiring the infrastructure to carry out CAR T-cell therapy in the outpatient space, because the main campus did not initially have space to accommodate outpatient administration. Since St Luke's Cancer Institute is not-for-profit, it needed to raise funds to build the foundations and bring in equipment. Community fundraisers have played an integral part in securing the necessary funds for physical space and continue to be a prominent source of funds for the institution's ongoing CAR T-cell therapy efforts.

St Luke's Cancer Institute has also partnered with local charity organizations that have offered to match community donations raised by the institution over an extended period. For instance, in the most recent donation drive, the Holland M. Ware Charitable Foundation committed to donating \$500,000 to St Luke's if the institute could raise \$250,000 in 100 days.

### TIP

Other organizations that find themselves in a similar position of lacking the initial resources to implement outpatient CAR T-cell therapy may also consider community fundraising as a method of meeting infrastructure goals.

### Conclusion

CAR T-cell therapy is ushering in a new era of cellular therapies that are changing the very definition of cancer treatment. Though these treatments have great potential, they are still predominantly confined to large academic centers and are therefore inaccessible to many patients across the country. There is an increasing need to shift as many as of these therapies as feasible to community oncology settings to expand access, control healthcare costs, and increase convenience for patients. Integrating CAR T-cell therapies into community practices requires a significant amount of infrastructure and planning and—most importantly—a dedicated team of local experts who are committed to the cause. The transition to outpatient administration is not a simple undertaking, but it is a critical step in the optimization of these life-saving therapies.

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