Outpatient Administration of Chimeric Antigen Receptor T-Cell Therapy Using Remote Patient Monitoring

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ABSTRACT

Chimeric antigen receptor T-cell (CAR-T) therapies are standard of care for the treatment of several hematologic malignancies. Although patients receiving CAR-T therapies are frequently hospitalized given risks of cytokine release syndrome (CRS) and immune effector cell–associated neurotoxicity syndrome (ICANS), there is increasing interest and evidence for the safety of their outpatient administration. We review various models of care and provide operational considerations for centers that are interested in developing outpatient CAR-T programs, with a particular emphasis on using remote patient monitoring (RPM) to facilitate outpatient care. Safe and high-quality outpatient care requires involvement of a multidisciplinary team with clinical pathways for rapid triage and evaluation for CRS and ICANS and their management and, if necessary, timely transition of patients to a higher level of acute care. RPM can facilitate scaling an outpatient program in a cost-effective manner, especially across multiple sites of care, and can reduce the time patients spend in an acute care setting. Overall minimizing hospital-based care and an outpatient approach can alleviate capacity challenges treatment centers have faced that have partly impacted access to CAR-T therapies and have the potential to positively impact patient and caregiver experience and quality of life.

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INTRODUCTION

Chimeric antigen receptor T-cell (CAR-T) therapies are approved by the US Food and Drug Administration (FDA) for B-cell lymphomas, B-cell ALL, multiple myeloma, and chronic lymphocytic leukemia and are under clinical investigation for other hematologic malignancies, solid tumors, and autoimmune diseases.[1-3] Pivotal clinical trials of CAR-T focused on patients with relapsed/refractory ALL and large B-cell lymphoma and were exclusively conducted in the inpatient setting where patients were hospitalized from the initiation of lymphodepleting chemotherapy to 10-14 days after CAR-T infusion.[4-6] This was due to the recognition that there was a high incidence of quick onset and life-threating toxicities that needed close monitoring and immediate treatment (cytokine release syndrome [CRS] and immune effector cell–associated neurotoxicity syndrome [ICANS]).[7] Subsequent clinical trials have led to additional approvals in lymphoma and myeloma and have also favored inpatient administration and post-infusion care for close monitoring for CRS and ICANS.[8-13] Over the past decade, supportive care and management of CRS and ICANS have significantly improved with greater clinical experience. In combination with the development of guidelines and prophylactic strategies to reduce associated toxicities, there has been increasing interest in moving the care of CAR-T recipients to the outpatient setting.[1,7,14-18]

There are advantages to outpatient delivery of CAR-T therapies, reserving hospitalization for selected patients and for the management of toxicities. Patients might have a reduction in hospitalization-associated risks such as hospital acquired infections and improvement in patient satisfaction and quality of life. Outpatient administration may also reduce pressures on inpatient capacity constraints and nurse staffing, a known barrier to the number of CAR-T procedures that can be performed at institutions. In addition, outpatient care is less costly for health systems.[19] Previously, outpatient administration was more favorable for reimbursement for patients covered by Medicare although this has become less of a concern as the Centers for Medicare and Medicaid Services payment methodologies for CAR-T have evolved. However, patients require additional education and support and the treatment center needs to make additional investments in personnel and infrastructure for successful outpatient CAR-T administration. An expert panel convened by the American Society for Transplantation and Cellular Therapy (ASTCT) has elaborated on the pros and cons of providing outpatient CAR-T therapy and considerations for developing a program.[20]

The literature on outpatient CAR-T therapy is limited to small single-center experiences that are reflective of local resources and treatment patterns, is mostly focused on

outcomes, and offers few details about operationalizing an outpatient program, and hence, it is challenging to generalize and scale across larger health systems.[21-27] The Sarah Cannon Transplant and Cellular Therapy Network (SCTCTN) includes five Foundation for the Accreditation of Cellular Therapy (FACT)–accredited centers in the United States that provide FDA-approved and investigational immune effector cell therapies (IECTs). These centers collectively function as one program with standardized clinical pathways, supportive care guidelines, and a single quality plan. SCTCTN has implemented outpatient CAR-T programs across four IECT centers that are supported by remote patient monitoring (RPM) and cared for more than 200 recipients of FDA-approved CAR-T products for ALL, lymphoma, and myeloma in 2024. In this clinical review, we use our experience to share clinical and operational considerations for an outpatient CAR-T program.

CONSIDERATIONS FOR OUTPATIENT ADMINISTRATION OF CAR T-CELL THERAPY

Models for outpatient CAR-T therapy need to adapt to patient needs, referral and catchment area, current and projected IECT procedure volume, local infrastructure, inpatient and outpatient capacity, and institutional ability to make capital and personnel investments in the program. In the near future, we anticipate that these therapies will be increasingly administered across multiple sites of care and care models that can be implemented and scaled across diverse health systems are needed. This is especially relevant as practices and hospitals that have traditionally shied away from transplantation and cellular therapy are evaluating options for providing CAR-T therapies.

Table 1 outlines high-level considerations to establish and operate an outpatient CAR-T program. Figure 1 shows a schematic of our operational workflow for patients receiving outpatient CAR-T therapy. Our approach is product- and diagnosis-agnostic and follows defined eligibility criteria for outpatient care that includes patient age, performance status, reliable caregiver support, distance of residence from the treatment center or availability of local lodging, and the ability to use RPM. Care is coordinated through physician-developed standardized clinical pathways and standard operating procedures (SOPs) that are applied across multiple sites, such as for outpatient patient assessment and monitoring, and evaluation and management of CRS and ICANS. Furthermore, triage decision trees facilitate timely transition to inpatient or hospital observation setting, if clinically indicated.

Acute care hospital emergency departments (EDs) often face staffing and capacity issues and can be a barrier to successful implementation of an outpatient CAR-T program. It is critical that gaps in ED workflows (eg, ability to rapidly triage CAR-T recipients, placement in a private room), staff education (eg, care of immunocompromised patient, management of CRS and ICANS), and pharmacy operations (eg, ability to administer tocilizumab, timely administration of antibiotics in neutropenic patients) be addressed early in the planning process. Establishing communication and handoff protocols between the primary team and ED is also important, especially for timely decision making for administration of tocilizumab. Once the program gets established, ongoing education of ED clinical staff is also needed since this area of the hospital frequently has high rates of personnel turnover. Of note, some centers have care models where transplant and cellular therapy patients can be admitted directly to the inpatient unit and can bypass the ED.

For CAR-T products that currently have FDA approval, the reported incidence of any-grade CRS and grade ≥2 CRS is 50%-80% and 10%-50% and that of any-grade ICANS and grade ≥2 ICANS is 40%-80% and 10%-40%, respectively.[2,7,28,29] Hence, a significant number of patients who receive outpatient CAR-T therapy may require hospitalization for the management of toxicities. Care in the outpatient setting, however, reduces the number of days spent in the hospital and presents an opportunity to optimize time in hospital for windows with actionable intervention compared with care provided completely inpatient. This again emphasizes the need for care pathways, electronic health record tools, and ongoing education that facilitates timely transition to higher-level care to prevent adverse outcomes from CRS and ICANS.

To ensure the safety and efficacy of CAR-T products administered in the outpatient setting, a comprehensive quality program is essential. Programs accredited by FACT will have the foundational aspects of a quality program. Other programs that are new to cellular therapy can refer to a framework for an IECT quality program that has been proposed by the ASTCT.[30] In addition to standard structural, process, and outcome measures that an IECT program may follow, some examples of quality metrics to track specifically for outpatient CAR-T therapy include timing and rates of hospitalization and intensive care unit–level care, time to administration of tocilizumab, rates of higher grades of CRS and ICANS, length of stay in the hospital, readmission rates after any initial hospitalization, measures of patient and caregiver satisfaction, and patient-reported outcomes. Where a program implements RPM, additional measures may be considered to ensure timely recognition of CRS and triage and transition of care to appropriate setting (Table 2).

Financial considerations are another aspect of an outpatient CAR-T program, especially as an institution weighs investments in clinic infrastructure and personnel, including RPM care models. The business case should consider anticipated current and future volume of CAR-T recipients at a center along with inpatient bed capacity and clinic space. Resources dedicated toward outpatient CAR-T also have the potential to support outpatient hematopoietic cell transplants and other therapies such as bispecific T-cell engagers. The contracting and reimbursement teams need to gain experience in establishing appropriate agreements with various payers including complex global billing procedures

TABLE 1. Considerations for Establishing and Operations for an Outpatient CAR-T Program

Patient and caregiver
Patient
Eligibility criteria (eg, based on age, comorbidities, performance status)
Availability of local lodging
Patient education on the CAR-T process, toxicities, and RPM
Psychosocial assessment
Caregiver
Reliable caregiver support and transportation plan
Caregiver education on CAR-T process, toxicities, and RPM
Psychosocial assessment
Technology assessment (for RPM)
Connectivity
Patient and caregiver education
Run in period
Operations
Clinical pathways and SOPs
Clinical pathways (eg, patient selection, CRS and ICANS management, antimicrobial prophylaxis)
Process SOPs (eg, cell processing laboratory, pharmacy, outpatient care, transition to inpatient or hospital observation)
Quality SOPs (see below)
Product-specific SOPs
RPM pathway for alarm trigger and prompt local triage
Emergency department
ED rapid triage protocol
ED staff training on identifying and treating CRS and ICANS
Pathways and order sets for administration of tocilizumab in ED
Handoff protocols between the primary team and ED
Workflows for timely transfer of patients from ED to appropriate inpatient unit
Pharmacy
Ordering and management of lymphodepleting chemotherapy
Product labeling
Tocilizumab availability
Nursing
Standardized process for infusion of CAR-T
Standardized assessment of patients
Evaluation and grading of CRS and ICANS
Care coordination
Laboratory services
Turnaround time for outpatient laboratories (eg, CBC counts, electrolytes and renal function, C-reactive protein, ferritin level)
Electronic health record
Standardized order sets for various aspects of outpatient CAR-T administration
Standardized templates for documentation including grading of CRS and ICANS
Education
Initial onboarding and ongoing education of program personnel on outpatient CAR-T
Education of outpatient care team on RPM technology and clinical monitoring service protocols
Education of ER personnel on rapid triage and management of CRS and ICANS
Education of other personnel who may manage CRS and ICANS (eg, hospitalists)
Quality
Compliance with FACT standards
Outcome and process quality metrics
Compliance with REMS requirements

(continued on following page)

TABLE 1. Considerations for Establishing and Operations for an Outpatient CAR-T Program (continued)

Process for review and mitigation of quality events
Infrastructure
Optimize infusion or day hospital space
Optimize clinic throughput and workflows
Adequate nurse staffing to support outpatient care
Infrastructure for rapid triage to inpatient (eg, hold bed agreement)
Resource for educating various personnel
Finance
Preauthorization
Contracts and single case agreements
Accurate billing, submission of claims, and reimbursement

Abbreviations: CAR-T, chimeric antigen receptor T-cell; CRS, cytokine release syndrome; ED, emergency department; FACT, Foundation for Accreditation of Cellular Therapy; ICANS, immune effector cell–associated neurotoxicity syndrome; REMS, risk evaluation and mitigation strategies; RPM, remote patient monitoring; SOPs, standard operating procedures.

and optimize billing for the care received in the outpatient and inpatient settings. Fortunately, there are data available such as rates of hospitalization and hospital length of stay that can inform centers that are planning to establish an outpatient CAR-T program.

RPM FOR CAR-T THERAPY TOXICITY

In our experience, RPM has assisted in scaling a standardized outpatient program across multiple sites of care. Our RPM platform is supported by a clinical monitoring service that is staffed by trained nurses who monitor for CRS alarms and vital sign trends of clinical concern and connect with patients by phone or video chat to rapidly triage patients to the right local site of care. While local providers are involved, physician-developed algorithms defined by the SCTCTN guide decisions on when to escalate the level of care (Table 2 and Fig 1). The overall premise of this approach is to identify CRS early and intervene in a timely manner to prevent its progression to higher grades.[31-33]

We have observed several advantages of using RPM to support our outpatient CAR-T program. Patients and caregivers have provided feedback that their knowing a nurse is monitoring for toxicity and available 24/7 allays their anxiety and enhances confidence in receiving outpatient care. From a treatment center standpoint, patients may require less on-site monitoring in an outpatient clinical setting. Clinician facing web-based dashboards allow the local clinical team to monitor all patients receiving CAR-T therapies at a given center. Although there are additional expenses in integrating RPM technology and clinical monitoring services from a third-party vendor, these may be offset by a reduction in costs associated with inpatient utilization and the benefit of optimizing inpatient and outpatient capacities.

There are a spectra of RPM devices, platforms, and care models that can apply to outpatient CAR-T therapy. These range from wearable devices where vital signs are self-monitored by patients, to devices that passively monitor and transmit vitals to a local treatment center, to a full-service platform similar to the one we use at SCTCTN (Current Health Gen 2, Best Buy Health Inc, Boston, MA). An important tenet of a successful model is a trained individual to monitor RPM outputs, rapidly identify clinically relevant issues, and escalate them in a timely manner for appropriate management. Ultimately, the technology must serve patient and treatment center requirements. Factors such as the patient population being treated, current and future inpatient and outpatient capacities, ability to provide local clinical care and technology support, and emergency department and after-hours clinical support are key when investing in an RPM platform and determining which care model will best address local needs. FDA 501(k) clearance is the minimum bar for wearable devices to ensure that patients and providers are receiving reliable RPM data for clinical decision making. It is also important to consider that FDA clearance does not indicate user-friendliness of a particular device for patients, its adherence, or how well a device will perform in a patient's home.[34] Individual centers with relatively small IECT procedure volumes or with substantial existing outpatient transplant and cellular therapy infrastructure can provide outpatient CAR-T therapy care without RPM although such care models are challenging to scale up for broader application or translate to other settings. In addition, the burden on patients and caregivers in these models has not been well described.

SCTCTN EXPERIENCE WITH OUTPATIENT CAR-T USING RPM

The SCTCTN has implemented an outpatient CAR-T program across four sites using physician-developed clinical pathways and standard operating procedures (Fig 1).[35] Patients who are eligible to receive outpatient care are enrolled on an FDA-cleared third-party RPM platform before initiation of lymphodepleting chemotherapy. They receive a kit that consists of a tablet and a multidevice charging platform,

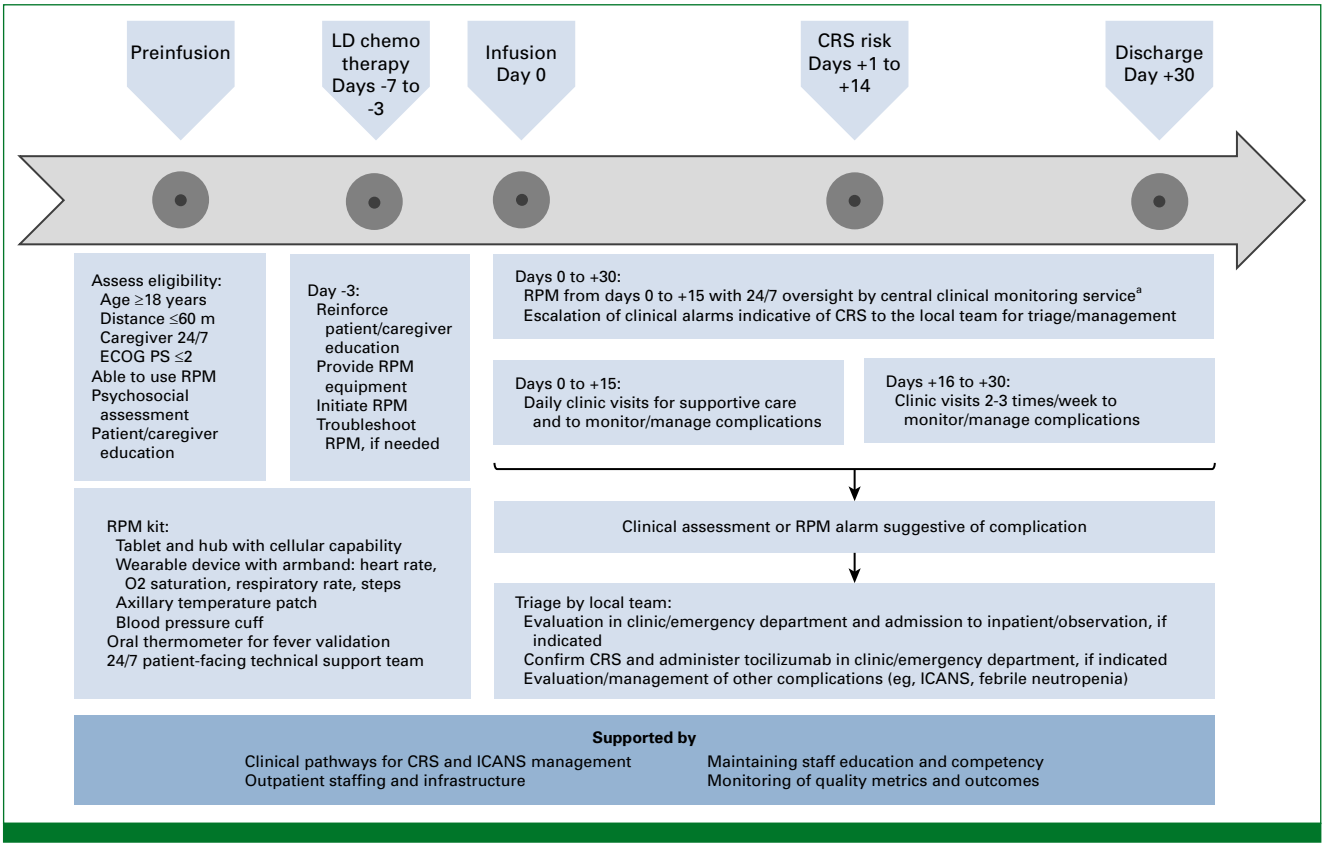

FIG 1. Patient assessment and operational workflow for outpatient administration of CAR-T therapy using remote patient monitoring. [a]RPM can be extended beyond day +15 by the local team in case longer monitoring is clinically indicated. CAR-T, Chimeric antigen receptor T-cell; CRS, cytokine release syndrome; ECOG PS, Eastern Cooperative Oncology Group performance status; ICANS, immune effector cell–associated neurotoxicity syndrome; LD, lymphodepletion; RPM, remote patient monitoring.

a hub with cellular capability, an axillary temperature patch, a blood pressure cuff, an FDA-approved oral thermometer for fever validation, and a wearable device with armband that monitors heart rate, oxygen saturation, respiratory rate, and steps. As noted above, a multidisciplinary team developed standardized algorithms for wearable alarm triggers and pathways for triage and management of CRS and ICANS. A central clinical monitoring service staffed by trained nurses monitors RPM data 24/7, calls patients when alarms are triggered to exclude false positives (eg, validate fever detected by axillary temperature patch with an oral thermometer reading), escalates clinical concerns to providers locally at treatment centers, and coordinates patient triage to clinic or ED for in-person assessment and subsequent management. Monitoring is started on day −3 so that patients have time to get comfortable with RPM and any technical issues can be resolved before the day of CAR-T infusion. Patients have in-person daily clinic visits with a provider during the highest risk period for CRS and ICANS (through day +14), with less frequent engagements subsequently based on clinical needs and the presence of complications.

Our observations in a recent analysis of 209 patients monitored through day +30 after infusion will be informative for other centers considering outpatient care for CAR-T recipients.[36] In this contemporary cohort (February 2023-June 2024) of adult patients with a median age of 64 years, 56% had non-Hodgkin lymphoma, 34% had multiple myeloma, and 10% had ALL. Using the performance status, comorbidity, and psychosocial support criteria outlined above, more than 80% of patients under consideration for CAR-T therapy using FDA-approved products were eligible and opted to receive their care through the outpatient program. Although there was variation by site, overall 70%-79% of patients developed any-grade CRS and 29%-33% of patients developed any-grade ICANS. However, with our pathways for early management of toxicity, only 4%-5% of recipients experienced grade ≥3 CRS and 6%-9% experienced grade ≥3 ICANS. Overall, 98% of CRS and 96% of ICANS episodes occurred within the first 15 days of CAR-T infusion. Beyond the first 15 days, no patient developed grade 3 or 4 CRS and only one patient developed grade 3 ICANS. During the first month, 82%-86% of patients needed hospitalization for management of CRS, ICANS, or other complications, and the median duration of hospitalization ranged from 4 to 6 days across the four sites. For illustration purposes, the average duration of hospitalization was 16 days for CAR-T recipients who did not meet criteria for outpatient administration and received planned

TABLE 2. Examples of Remote Patient Monitoring Alarms Among CAR-T Therapy Recipients Who May Require Escalation of Clinical Issues for Further Evaluation and Management

Clinical Alarms
Fever (median axillary temperature ≥37.4°C for 30 minutes or single axillary temperature of ≥38.5°C)
Hypoxia accompanied by at least one other vital sign outside of normal limits
Heart rate and respiratory rate outside of normal limits
Systolic and/or diastolic blood pressure outside of the normal range
Alarms that repeat ≥4 times in 4 hours
Patient initiated "I need help" feature on the tablet
Technical alarms
No data for >4 hours (triggered without corresponding known event explaining data interruption)
Low battery alarm

inpatient care. The overall survival at 30 days ranged from 97% to 98% for outpatient CAR-T recipients. We observed a high rate of wearable device adherence for the duration of RPM (median 84%-86% across programs, which is considered sufficient for monitoring). The similarity in rates of hospitalization, complications, and overall survival across the four sites of care demonstrates the value of consensus guidelines and standard operating procedures to maintain safety and quality in a treatment network.

Overall, our experience suggests that a structured program supported by RPM can facilitate safe outpatient administration of currently FDA-approved CAR-T products. Patients require close clinical monitoring primarily during the first 2 weeks after infusion to mitigate risks associated with CRS and ICANS. Hospitalizations for CRS occur at predictable times after infusion, aligned with those reported in the literature, and the length of stay is of relatively short duration.[37] The rather high rate of hospitalization for the evaluation and management of CRS, ICANS, and other toxicities that we have observed is similar to what has been recently reported in the literature by other smaller series of outpatient CAR-T (reported range, 70%-90% within the first 30 days).[21-23,27] However, we do anticipate that the need for escalation of care and hospitalization rates will decrease with greater experience with outpatient care.

FUTURE DIRECTIONS

Access barriers have prevented CAR-T therapies from realizing their full potential in treating patients with hematologic malignancies.[38-40] Capacity challenges at IECT treatment centers have been identified among factors that may limit the number of patients who can receive this therapy. These issues will likely worsen with the anticipated increase in the number of patients who need cellular therapies, especially as the field progresses toward safer products with more favorable toxicity profiles, additional future indications in solid tumors and autoimmune diseases, and competing priorities among an increasing number of IECT clinical trials. Newer models of care delivery are urgently needed to adapt to these unmet needs. Exploring and validating outpatient delivery of CAR-T therapy is an opportunity to address capacity issues that may limit access. These models will assist development of newer IECT programs in community oncology practices that are predominantly equipped to provide outpatient cancer care. Innovation in regulatory framework will also help, where outpatient care delivery models are incorporated within clinical trial designs that lead up to FDA approval, and trials are site of care agnostic with inpatient *v* outpatient administration determined by the risk and severity of toxicities. Notably, an analogous approach can be applied for step-up dosing required for T-cell engager therapies, which are associated with similar toxicities of CRS and ICANS.

Given the diversity of the US health care system, a spectrum of outpatient CAR-T care models is needed for greater penetration into treatment sites, and clinical trials and observational studies that provide information on their feasibility, operations, resource utilization, cost-effectiveness, and outcomes are needed. These data will guide implementation of various care models (eg, RPM *v* patient self-reported identification of CRS, shared care between treatment centers and community oncologists, etc) across a variety of health care settings. Research also needs to focus on patient-centered outcomes in outpatient CAR-T recipients such as quality of life and patient-reported outcomes. There is an opportunity to develop and validate digital end points in passively monitored cohorts of CAR-T recipients. Some examples where such end points can be of value include comparative effectiveness research of CAR-T therapies for the same indication and providing data to support implementation of a variety of postapproval care delivery models. Finally, health policy–level research will also be critical to ensure that payment and reimbursement models innovate to support the evolution of clinical care models for CAR-T recipients.

Our model of providing outpatient care to CAR-T therapy recipients using RPM across a multicenter network can serve as a guide for other institutions considering this approach within their IECT programs. Models of outpatient CAR-T care that do not use RPM have been reported or are under investigation. Collectively, these models expand the menu of options for treatment centers to adopt for outpatient CAR-T and will ultimately increase access to patients who have the potential to benefit from these transformative therapies.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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Outpatient Administration of Chimeric Antigen Receptor T-Cell Therapy Using Remote Patient Monitoring

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