

Research

Implementation of a lisocabtagene maraleucel chimeric antigen receptor T-cell therapy outpatient monitoring program: Multicenter nursing/advanced practice provider perspectives

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ABSTRACT

Objectives: Lisocabtagene maraleucel (liso-cel; Breyanzi), an autologous chimeric antigen receptor T-cell therapy, has demonstrated efficacy and safety in relapsed/refractory large B-cell lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma, follicular lymphoma, and mantle cell lymphoma. Outpatient monitoring after liso-cel administration has shown lower health care resource utilization and cost and high patient satisfaction. However, outpatient monitoring programs require well-designed processes with collaborations from multiple stakeholders across several facilities. The study objective is to provide learnings and key considerations from nurses and advanced practice providers (APP) with experience setting up and managing liso-cel outpatient monitoring programs.

Data source: Author experience gathered from 3 institutions at 2 workshops.

Results: In the reviewed programs, patients are discharged on the same day after liso-cel infusion and observation. They are required to remain within a short distance of the facility for ≥ 4 weeks with admission to treatment facilities upon experiencing adverse events (AE). Nurses/APPs report several key features of successful programs: flexibility to carry out essential roles/functions based on institution's resources and staff structure, a phased or hybrid (hospital/clinic) approach to program launch, a core team to run and guide the program, robust training for staff, options to tailor AE monitoring based on institution guidelines, and coordinated transitions between multiple stakeholders and facilities.

Conclusions: Nurses/APPs are critical contributors to liso-cel outpatient monitoring programs. Success in providing appropriate, complex individualized care in these programs can be achieved by using a multistakeholder approach with appropriate staff and patient/caregiver training and careful coordination across multiple functions and facilities.

Implications for nursing practice: The learnings and resources presented may provide insight to considerations around the development of a cell therapy outpatient monitoring program. However, the information provided here should be taken together with other relevant resources and guidelines and should be adapted to align with the institution's own guidelines.

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Introduction

CD19-directed chimeric antigen receptor (CAR) T-cell therapies, including lisocabtagene maraleucel (liso-cel; Breyanzi), axicabtagene ciloleucel (Yescarta), and tisagenlecleucel (Kymriah), have demonstrated efficacy and safety in multiple hematologic malignancies.^{1–4} Liso-cel is approved in the United States (US) and European Union for the treatment of adult patients with large B-cell lymphoma (LBCL),

including diffuse LBCL (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy, or refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation due to comorbidities or age, or relapsed/refractory (R/R) disease after ≥ 2 lines of systemic therapy.^{3,5} It is also approved in the US for adult patients with R/R chronic lymphocytic leukemia or small lymphocytic

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Layperson Summary

What we investigated and why

Lisocabtagene maraleucel is a type of treatment for relapsed/refractory large B-cell lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma, follicular lymphoma, and mantle cell lymphoma. Administration and outpatient monitoring of lisocabtagene maraleucel may reduce resource use and cost while maintaining efficacy and safety similar to the inpatient setting. Developing an institutional program for lisocabtagene maraleucel administration and outpatient monitoring is a complex task. We wanted to understand the key elements utilized by select chimeric antigen receptor T-cell treatment centers for successfully setting up their programs.

How we did our research

Nurses and advanced practice providers from 3 lisocabtagene maraleucel outpatient monitoring programs collected their key learnings and practical considerations for setting up and managing these programs successfully.

What we have found

Nurses and advanced practice providers are critical contributors to lisocabtagene maraleucel outpatient monitoring programs. There is flexibility to design the programs best suited to the existing structure, available resources, and treatment/monitoring guidelines at each institution. Success in such programs can be achieved by engaging multiple stakeholders, appropriately training staff and patients/caregivers, and carefully coordinating the treatment and adverse event monitoring process across multiple functions and facilities.

What it means

The learnings and resources presented may provide insight to considerations around the development of a cell therapy outpatient monitoring program. However, the information provided here should be taken together with other relevant resources and guidelines and should be adapted to align with the institution's own guidelines.

lymphoma who have received ≥ 2 prior lines of therapy, including a Bruton tyrosine kinase inhibitor and a B-cell lymphoma 2 inhibitor; adult patients with relapsed or refractory follicular lymphoma who have received 2 or more prior lines of systemic therapy; and adult patients with relapsed or refractory mantle cell lymphoma who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase inhibitor.³

In clinical trials and early real-world treatment experience with CAR T-cell therapies, inpatient administration and monitoring was preferred because of the complexity of the treatment and concerns about management of adverse events (AE), specifically cytokine release syndrome (CRS) and neurological events (NE), which are associated with CAR T-cell therapies.^{6,7} As knowledge and understanding of the efficacy and safety profiles of CAR T-cell therapies grows, CAR T-cell centers, including community centers, are increasingly interested in the outpatient monitoring of patients after liso-cel administration, due to its established safety profile with low incidence of grade ≥ 3 CRS and NEs and delayed onset of CRS (median time from infusion to onset of 5 days [range 1-14] in patients with R/R LBCL).⁸⁻¹²

OUTREACH (NCT03744676), the first and largest study to prospectively assess CAR T-cell therapy in the community setting with the

option for outpatient monitoring, evaluated liso-cel as third-line or later treatment in patients with R/R LBCL at qualified community/nonuniversity medical centers in the US.¹³ In OUTREACH, 24% of outpatients were never hospitalized after liso-cel infusion. Liso-cel demonstrated comparable efficacy and safety in inpatients and outpatients with similar response rates and incidence of CRS and NEs, supporting liso-cel administration at appropriately selected community sites and feasibility of outpatient monitoring at sites appropriately resourced and structured.¹³ In a study investigating the economic differences of CAR T-cell therapy administration by site of care, outpatient monitoring programs showed reduced total costs of care.¹⁴ In a retrospective analysis of TRANSCEND NHL 001 (NCT02631044), a multicenter, seamless design, phase 1 study of liso-cel in R/R LBCL, outpatients with CRS/NEs had lower health care resource utilization and lower median costs for AE management compared with inpatients, further supporting outpatient monitoring after liso-cel administration.¹⁵ Other possible advantages include less exposure to potential hospital infections, more touchpoints for emotional support from caregivers and social network, increased mobility to assist physical recovery, better nutrition support (especially for patients with special dietary preferences), flexibility to schedule monitoring/follow-ups based on patients' schedules, improved accommodation options for caregivers considering that not all hospitals have available beds/lodging (caregivers may stay at a hotel/home rather than on a chair in the hospital), and better resource utilization at hospitals.

In clinical practice, outpatient monitoring after liso-cel administration has been successful at multiple centers with appropriate resources and risk mitigation strategies. Nurses, advanced practice providers (APP), nursing coordinators, and nurse educators play a crucial role in the management of patients throughout the treatment process and in ensuring the success of outpatient monitoring programs. The objective of this study is to provide a broad overview of the liso-cel outpatient monitoring process from nurses and APPs at 3 different institutions that administer CAR T-cell therapies, with a focus on key learnings and practical considerations. Similar to previous publications focused on sharing important nursing considerations of new oncology outpatient processes to facilitate adoption,¹⁶⁻¹⁸ we report several key features of successful liso-cel outpatient programs, including flexibility to carry out essential roles/functions based on institution's resources and staff structure, a phased or hybrid (hospital/clinic) approach to program launch, a core team to run and guide the program, robust training for staff, options to tailor AE monitoring based on institution guidelines, and coordinated transitions between multiple stakeholders and facilities.

Methods

Two workshops (1.5 hours each) with moderated discussions were conducted virtually to gather key learnings and practical considerations for the liso-cel outpatient monitoring process from nurses and APPs at 3 different institutions that administer CAR T-cell therapies. Each institution represented in these workshops, Rutgers Cancer Institute/Robert Wood Johnson University Hospital, Swedish Cancer Institute, and Mayo Clinic (Mayo Clinic utilizes only outpatient monitoring after infusion), has had decades of experience in transplantation and cell therapy administration (Table 1). The nurses and APPs each bring over 30 years of professional experience, including in cell therapy, showcasing extensive expertise and deep involvement in the field. The perspectives shared in this manuscript were based on workshop summaries and independently reviewed and finalized by authors. Anecdotal patient experience was gathered retrospectively and provided by authors. Institution and program information were derived from institutional records.

TABLE 1
Summary of CAR T-Cell Therapy Outpatient Monitoring Programs^a

	Institution 1	Institution 2	Institution 3
Transplantation and cell therapy experience, years	30	20	61
CAR T-cell therapy infusion experience, years (range)	6 (2018–2024)	5 (2019–2024)	4 (2020–2024)
Outpatient monitoring experience, years (range)	3 (2021–2024)	4 (2020–2024)	4 (2020–2024)
Number of patients infused with CAR T-cell therapy per year			
2022	42	13	102
2023	60	20	133
Patients who received outpatient monitoring, n/N (%)			
2022	13/42 (30)	13/13 (100)	82/102 (80)
2023	24/60 (40)	20/20 (100)	117/133 (88)

CAR, chimeric antigen receptor.

^a From institutional records.

Overview of a Liso-Cel Outpatient Monitoring Program

Similar to inpatient care, liso-cel administration in the 3 outpatient monitoring programs reviewed here (Table 1) occurs in a highly controlled setting, either in a hospital-based outpatient infusion center or an oncology clinic with a separate, associated hospital (Fig. 1). Before enrolling in the outpatient monitoring program, the patient is assessed to determine their eligibility. Patients who are eligible to participate based on the treating physician's decision, along with their caregivers, will receive assessments to determine individual needs and focused education that prepares them for the monitoring of AEs (eg, CRS and NEs) outside of the treatment facility. Nurses support liso-cel infusion at the facility, after which the patients are placed under observation by nurses for approximately 4 to 8 hours to

monitor for AEs that might occur immediately after infusion. After the immediate observation period, the patient is discharged, but is required to remain within a short distance of the facility for ≥ 4 weeks. The exact distance is subject to the most recent policy requirements and institution guidelines; the 3 institutions reviewed in this manuscript require patients to stay within a 30-minute to 1-hour drive. The outpatient monitoring of AEs is achieved through a combination of regular clinic visits with nurses and patient/caregiver monitoring and reporting and may or may not include a component of telemedicine technology or monitoring devices. Patients can remain in the outpatient setting for the duration of their care, provided they do not experience CRS/NEs or any other complications.

Practical Considerations for a Liso-Cel Outpatient Monitoring Program

A successful outpatient monitoring program for liso-cel relies on a multidisciplinary approach and seamless transitions along the patient journey (Fig. 1) with collaborations from many individuals that may include nurses, APPs, physicians (including cellular therapy oncologists), apheresis nurses, cell therapy processing technicians, pharmacists, authorized representatives and/or quality managers, social workers, financial coordinators, patient advocates, and caregivers across multiple facilities. Example personnel and roles that are important in the execution of a successful outpatient monitoring program are described in Table 2. While these roles and responsibilities are critical, they may be carried out by personnel with different job titles depending on the resources and staffing structure at each institution.

Program Setup and Staff Training

It is important to acknowledge the resources required to set up and implement an outpatient monitoring program. At inception, it is key for a physician champion to engage facility leadership, evaluate

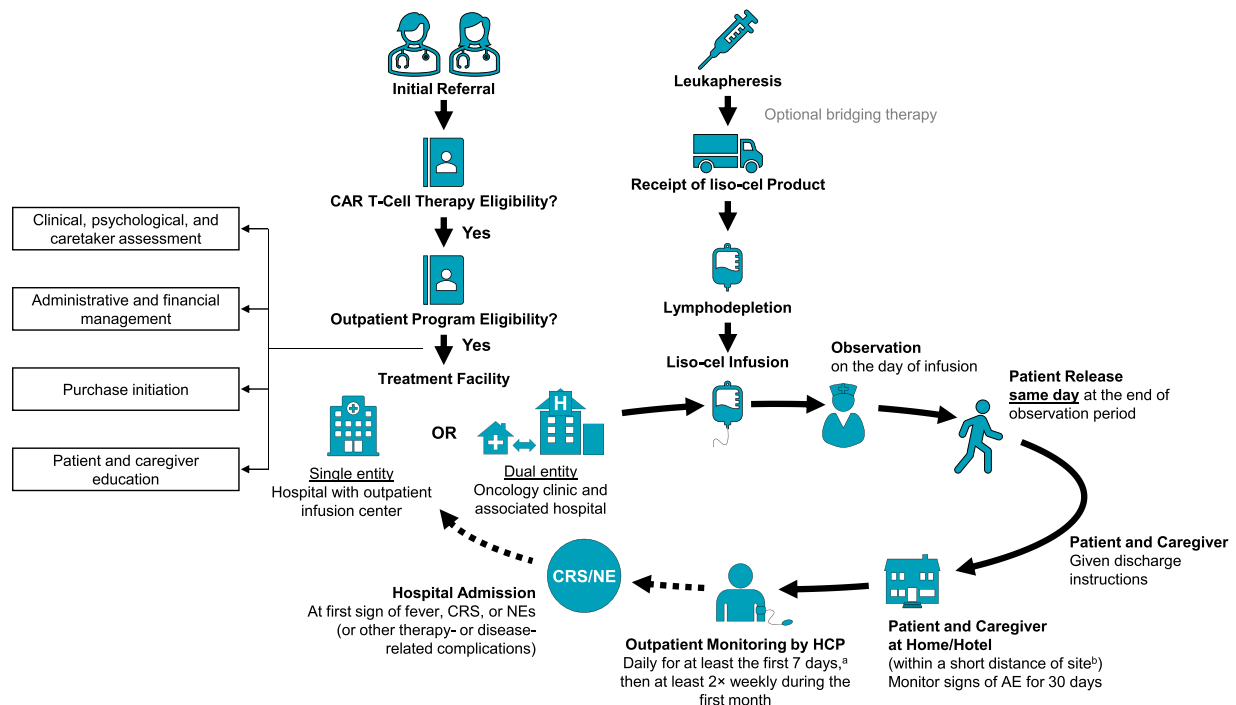


FIG 1. Liso-cel infusion and monitoring in outpatient setting. AE, adverse event; CAR, chimeric antigen receptor; CRS, cytokine release syndrome; HCP, health care professional; liso-cel, lisocabtagene maraleucel; NE, neurological event. ^aInstitution guidelines may require an extended daily check-in period of ≥ 8 days. ^bPatients and caregivers are required to stay within 2 hours of the site based on the current regulatory requirement; however, institution guidelines may require a shortened travel distance of within 30 minutes to 1 hour of the site.

TABLE 2
Example Personnel and Roles in Liso-Cel Outpatient Monitoring Programs

Personnel	Roles ^a
APP	<ul style="list-style-type: none"> • Process and standard operating procedure development • Support patient screening • Monitor and triage/coordinate care of potential AEs
Authorized representative and/or quality manager	<ul style="list-style-type: none"> • Support implementation and ongoing management of program requirements (eg, REMS, policies, procedures, and training)^b • Coordinate with team members, leaders, and manufacturer to ensure certification and compliance with REMS requirements
CAR T-cell therapy coordinator	<ul style="list-style-type: none"> • Organize and submit required documents, including financial authorization with financial coordinator • Manage scheduling of clinical services and other resources, including the infusion timing^c • Communicate scheduled components of complex care to patients/caregivers
Cell processing laboratory technician	<ul style="list-style-type: none"> • Coordinate liso-cel collection, storage, and delivery/receipt with manufacturer, apheresis staff, stem cell laboratory, and treatment staff^{c,d} • Manage the infusion timing^{c,d}
Financial coordinator	<ul style="list-style-type: none"> • Discuss coverage plan with patient • Support the patient with financial management • Obtain authorization by insurance providers
Nurse	<ul style="list-style-type: none"> • Manage/set up infusion equipment • Monitor and prepare patient for treatment • Perform infusions and train other nurses to perform infusions • Monitor for potential AEs after infusion • Provide patients/caregivers with discharge instructions and detailed education for monitoring of potential AEs while at home • Answer questions from patients/caregivers • Coordinate AE treatment with affiliated hospitals after discharge
Nurse educator	<ul style="list-style-type: none"> • Provide staff training • Offer patient/caregiver education^e
Pharmacist ^f	<ul style="list-style-type: none"> • Provide counseling and training on AE treatment to patients/caregivers, nurses/APPs, and/or medical fellows and residents • Inspect and dispense the infusion • Dispense AE treatment (eg, tocilizumab or corticosteroids)
Physician champion	<ul style="list-style-type: none"> • Engage leadership to secure support and needed resources • Advocate for, set up, and oversee the program
Primary oncologist	<ul style="list-style-type: none"> • Provide initial referral to the outpatient program • Monitor AEs of special interest, such as second primary malignancies, and treat potential AEs after the ≥ 4 weeks of monitoring period
Social worker	<ul style="list-style-type: none"> • Perform psychosocial assessment to determine patient eligibility • Evaluate caregivers, transportation, and lodging needs of patients • Coordinate care
Treating physician/oncologist	<ul style="list-style-type: none"> • Perform clinical assessment to determine patient eligibility • Order treatment • Monitor infusion process • Monitor and treat patient for potential AEs during the 30-day monitoring period

AE, adverse event; APP, advanced practice provider; CAR, chimeric antigen receptor; liso-cel, lisocabtagene maraleucel; REMS, Risk Evaluation and Mitigation Strategy.

^a The roles may be carried out by personnel with job titles that are different from those in the table as each institution has their own staffing structure. Some individuals may perform > 1 role. The list provided in this table is not intended to be comprehensive.

^b Training and education may be provided by a hematology or cellular therapy clinical nurse specialist at some institutions.

^c Roles may be performed by pharmacists at some institutions.

^d Roles may be performed by CAR T-cell therapy coordinators at some institutions.

^e Patient and caregiver training may be provided by CAR T-cell therapy coordinator at some institutions.

^f Liso-cel dispensing may be handled by cell processing laboratory technicians at some institutions.

staffing and training needs, and assess the capability of existing treatment and observation facilities to support such a program. If practical, a phased or hybrid approach between the clinic and hospital may be explored to bridge the divide between outpatient settings (clinics) and inpatient hospital care to support continuity of care. Structured ways to identify and address potential problems, or failures and their resulting effects on the program, such as Failure Mode and Effects Analysis, can improve the program design before launch.

It may be helpful to establish a core team with subject matter expertise in each function (eg, nurse, APP, clinic nurse specialist/nurse educator, financial coordinator, CAR T-cell therapy coordinator, social worker, pharmacist, authorized representatives and/or quality managers, and medical director). The core team would run the

program, develop educational materials and standard operating procedure (SOP), and set up training programs for an extended team. Offering training multiple times a year can accommodate new staff onboarding and the communication of SOP updates on a regular basis. Training in modular format with designated modules for each function and performed in person to allow hands-on practice and real-time feedback, and/or performed digitally/remotely for easy access has proven useful. A “see one, do one, teach one” approach¹⁹ can be employed to ensure competency in administering CAR T-cell therapy infusions. Designating time for training during work hours and creating a career ladder that incentivizes further education may help to improve engagement. Engaging the electronic health record (EHR) information technology team to build the required order sets

for CAR T-cell therapies before administering liso-cel can help to streamline internal operations and decision-making. These order sets typically cover treatment plans and AE management plans.

Outpatient Monitoring Program Eligibility and Enrollment

Before enrolling in an outpatient monitoring program, the patient typically receives clinical and psychosocial assessments from members of the core cellular therapy team (eg, oncologist, social worker, etc.) to determine their eligibility. If necessary, the patient may be referred to a psychologist for further evaluation and possible intervention before moving forward. CAR T-cell therapy coordinators may also coordinate care and utilize creative care models to ensure that the outpatient monitoring program is accessible to as many patients as possible. Social workers may evaluate caregivers, transportation, and lodging needs of the patient to ensure consistent and appropriate care can be provided in an outpatient setting. Caregivers must be ≥ 18 years of age, and functionally, physically, and cognitively capable. A caregiver must be able and available to provide assistance to the patient for 24 hours a day and 7 days a week for at least 4 weeks after infusion, consistent with outpatient monitoring of other CAR T-cell therapies. Sustainability of care by the caregiver may need to be re-evaluated during the outpatient monitoring period as the patient's situation evolves. A caregiver's responsibility can be performed by a single person or shared among several caretakers.

To offset the cost of lodging, negotiations for rates with hotels near the treatment facility and support for eligible patients from medical societies/foundations such as the American Cancer Society may be options patients can explore. Other options may include short- and long-term rentals, which may be open to negotiate discounted rates for an extended stay. Outpatient monitoring programs that build communication channels for patients and caregivers to provide feedback on their lodging experience during the required monitoring period have the advantage that necessary adjustments can be made quickly while informing lodging recommendations for future patients. Before initiation of a liso-cel purchase order, a financial coordinator may discuss a coverage plan with the patient, support the patient with financial management, and obtain authorization from insurance providers. A full staff briefing on the financial, lodging, and psychological needs of the patient before initiation of liso-cel infusion has proven useful in providing personalized patient care.

Patient and caregiver education is often launched at the enrollment stage with continued education throughout the patient journey; caregivers generally receive all education along with the patients. Education delivered as workshops by coordinators or nurses allows patients and caregivers to ask questions; digitally/remotely delivered education allows patients and caregivers to complete training at their own pace. Educational materials can be adapted from publicly available information, patient groups, foundations, and/or medical societies. Translation into other languages, especially Spanish, is useful.

Liso-Cel Infusion and Observation

It is important to ensure that the infusion facility has a precise workflow for delivering, receiving, and infusing the liso-cel product. It should also have the necessary equipment and adequate space for the infusion to support a seamless workflow. Vital to logistics is the role of a CAR T-cell therapy coordinator and/or cell processing laboratory technician who coordinates leukapheresis for liso-cel production, storage and delivery/receipt of liso-cel, and infusion timing with the manufacturer, apheresis staff, stem cell laboratory staff, pharmacy, and treatment nurses. Appropriate staffing with nurses, APPs, pharmacists, physicians, technicians, and/or coordinators for the

duration of preparation, infusion, and monitoring after infusion is very important (Table 2).

After infusion, patients in the reviewed programs are closely monitored for approximately 4 to 8 hours at the treatment facility. It is essential to ensure that the treatment facility has the capability and established SOPs in place to treat potential AEs, including the availability of tocilizumab. During observation, nurses and APPs play an important role in the early identification of AEs indicative of potential complications of therapy by monitoring for fever and changes in blood pressure and blood oxygen levels. Nurses and APPs also monitor for potential sepsis and infection in patients who may have received chemotherapy. When CRS and/or NE is suspected, nurses and APPs lead the assessment and grading of these events using available tools and guidelines.^{3,6} Nurses or APPs may reserve a designated or floating bed with the associated hospital. Such practices may be updated as the staff's comfort level grows. Some institutions may reserve hospital beds at the early stages of the program and then slowly adopt a more flexible process as staff gain experience.

Outpatients are released from the infusion facility on the same day at the end of the observation period. Before release, the patient and caregiver typically receive a comprehensive discharge outline (Supplementary Material 1) and education from nurses, including a schedule for follow-up visits, monitoring and reporting instructions for AE symptoms, and emergency contact information. Important information may be packaged as pocket cards (Supplementary Material 2) or refrigerator magnets for easy access.

Outpatient Monitoring

Outpatient monitoring takes coordinated collaborations and communication with patients, caregivers, and health care professionals. For ≥ 4 weeks after liso-cel infusion, patients and caregivers are required by the current regulatory policy to stay within 2 hours of the treatment facility to monitor for early signs of CRS/NEs or other AEs. However, many institutions recommend that patients and caregivers stay within a shorter distance of the site (eg, 30 minutes to 1 hour) based on institution guidelines. Rutgers Cancer Institute/Robert Wood Johnson University Hospital and Mayo Clinic require that patients and caregivers stay within a 30-minute drive of their sites, while the Swedish Cancer Institute requires a stay within a 1-hour drive. Self-monitoring may be achieved with on-body devices or daily logs. On-body devices or remote monitoring applications may be set up to push notifications to caregivers to prompt actions and/or directly to the EHR or to nurses/APPs. Evaluation of digital literacy of patients and caregivers may be needed when using remote monitoring; additional training is necessary for patients and caregivers who cannot properly use digital devices. Patients and caregivers use the educational materials as guidelines for AE monitoring and reporting but they require clear instructions on which center/health care professional to contact should AE symptoms emerge. An example of a care plan is provided in Supplementary Material 3.

Sites should have an established schedule for check-ins during the first ≥ 4 weeks. At the 3 institutions reviewed here, health care professionals typically conduct daily check-ins with the patient for ≥ 7 days after infusion, followed by ≥ 2 check-ins per week for ≥ 4 weeks. Institutions may have more stringent requirements, including an extended daily check-in period. One of the 3 institutions pushes notifications from the EHR to ensure regular follow-ups.

It is important that the flow of information for AE reporting during check-ins is clearly mapped out, or a triage system is set up, especially when using third-party vendors. For example, reports of AE symptoms may first go to nurses or APPs on call at the treatment facility or affiliated hospital, then the patient's treating physician is notified. Some institutions may choose to set up an on-call team, inclusive of physicians, that can provide coverage for AE symptoms reported during off business hours, weekends, and holidays. Third-

party vendors may offer triage services before the calls reach nurses, APPs, or the on-call team.

Admission for AE Monitoring and/or Management

At the first sign of fever, CRS, NE, or other therapy- or disease-related complications, patients are typically admitted to a hospital or hospital-affiliated clinic for further monitoring and may receive treatment for AEs if required. An inpatient oncology transition team may be useful to monitor bed utilization at the affiliated hospital to ensure quick admission and an available bed. Some programs use the emergency room (ER) as backup if the hospital is at capacity, or during weekends and holidays when the associated clinic is not operating. If beds are not available at the treatment facility, the patient may be required to visit an outside ER, in which case the patient and/or caregiver is advised to alert the ER that the patient has received CAR T-cell therapy and to ensure that their treating physician is notified. Some programs leave prompts in the EHR, such as “CAR T, no wait,” for next-stage health care professionals.

Transition of Care and Assessment of Program Impacts on the Patient

After the outpatient monitoring period of ≥ 4 weeks, comprehensive care for the patient typically transitions back to the patient's primary oncologist. Monitoring and treatment for AEs continues and broadens to focus on AEs of special interest such as second primary malignancies. It is recommended that outpatient monitoring programs gather feedback from patients and their caregivers to determine pain points in the program pathway and opportunities for improvements, excluding aspects that are mandated by regulatory and policy requirements.

In our assessment, the impact of liso-cel outpatient monitoring programs on qualified patients has been mostly positive. Overall and anecdotally, patients find the programs effective and efficient with flexibility to follow their own schedule, opportunity to spend more quality time with family and loved ones, and ability to maintain some normalcy outside of hospitals. Initial apprehension towards the program may be alleviated by continuously reinforcing the education and care plans. Patients have stated that they enjoy being able to maintain life outside of the hospital and spend more time with family and children, which may be more limited when undergoing monitoring and observation in a hospital setting. Patients have noted that having access to housing or local hotels near the hospital improved recovery, although there is a need for additional financial support for lodging. Patients who participated in an outpatient monitoring program at one of our institutions have reported that they were able to receive the care that they needed at any time and in a timely manner. Based on the experience at these institutions, patients and caregivers generally prefer the outpatient monitoring program to the inpatient program.

Conclusions

In both clinical trials and the real world, liso-cel outpatient monitoring programs have demonstrated comparable safety and efficacy to inpatient programs with lower health care resource utilization and cost. Anecdotally, patients and caregivers have stated that they prefer outpatient monitoring due to its effectiveness, efficiency, and flexibility. These observations are sparking interest in the development of outpatient programs. Nurses and APPs are critical contributors to the success of outpatient monitoring programs. The multicenter perspectives reviewed here, representing 3 different liso-cel treatment centers with outpatient monitoring across the US, may provide insight to the development of a successful liso-cel outpatient program, adding geographically diverse and balanced perspectives to single-institution experience previously reported.²⁰ Our collective experience

underscores that there is flexibility to set up liso-cel outpatient monitoring programs best suited to the existing structure and available resources at each institution. Success in providing complex individualized care to patients receiving outpatient monitoring after CAR T-cell therapy administration may be achieved by using a multistakeholder approach with appropriate staff and patient/caregiver training and careful coordination across multiple functions and facilities.

Declaration of competing interest

The authors declare the following financial interests/personal relationships, which may be considered as potential competing interests:

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Nicole McEntee: Writing – review & editing, Writing – original draft, Data curation, Conceptualization. **Jacqueline Manago:** Writing – review & editing, Writing – original draft, Data curation, Conceptualization. **ChiaChun Lu:** Writing – review & editing, Writing – original draft, Data curation, Conceptualization. **Lucy Holmes:** Writing – review & editing, Writing – original draft, Data curation, Conceptualization.

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Clinical Trial Registration

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