TRANSITIONING IMMUNOTHERAPY ADMINISTRATION TO THE OUTPATIENT SETTING: THE UCSF HEALTH EXPERIENCE

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Chimeric antigen receptor (CAR) T-cell therapy and bispecific T-cell engaging (BTCE) antibodies have transformed the treatment landscape for select hematologic malignancies, providing hope for patients with relapsed or refractory leukemia and lymphoma. These therapies have shown substantial clinical efficacy and are being rapidly developed for broader indications across the hematologic malignancy spectrum.[1,2,3]

Historically, both CAR T-cell and BTCE therapies have been administered in the inpatient setting. This was driven by the risk of acute toxicities, namely cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS), both of which can be severe and life-threatening without timely medical intervention.

However, confining these advanced therapies to the hospital setting is accompanied by significant challenges: high direct and indirect costs, prolonged hospital stays, increased risk of hospital-acquired complications and substantial resource utilization, particularly related to hospital bed occupancy. With increased experience with these therapies, clinicians have identified opportunities for shortened hospital stays and even complete outpatient care.

At University of California, San Francisco Health (UCSF Health), improving the patient experience has emerged as a key motivator for transitioning CAR T-cell and BTCE administration from the inpatient environment to outpatient clinics or even the home.[4,5]

Patients consistently cite preferences for recovery outside the hospital, improved autonomy, and reduced exposure to stressful or unfamiliar acute care environments.

Another major operational consideration has been the recognition that administration of these therapies constitutes a significant and growing portion of hospital bed utilization, displacing acute care beds that are critically needed for patients with complex clinical care needs. As demands for acute care resources have intensified, the organization needed to move eligible patients to the outpatient setting, thus maximizing patient-centeredness while increasing essential inpatient capacity for those who truly require it.

The right patient selection and infrastructure are essential to ensure that these therapies can be safely, efficiently, and appropriately administered in the outpatient setting.[4,5]

Safe and effective outpatient care is predicated on remote patient monitoring (RPM), rapid response protocols, and seamless coordination among multidisciplinary teams. These efforts achieve dual aims: enhancing the patient experience and reducing pressure on the healthcare system, while maintaining clinical safety and rigor.

CONSIDERATIONS FOR OUTPATIENT TRANSITION

▲ **Patient Selection:** Not all patients are appropriate candidates for outpatient CAR T-cell or BTCE administration. Careful, individualized selection is critical for optimizing safety and outcomes.

Appropriate criteria include reliable support from a caregiver, ability to remain within a one-hour drive of the treatment center during the high-risk periods (typically the first two to four weeks after infusion), absence of active central nervous system (CNS) disease, and lack of serious uncontrolled comorbidities.[6]

Patients also require the functional and cognitive capacity to report new symptoms promptly and adhere to monitoring protocols.

Other factors, such as disease burden, previous treatment toxicity, and logistical considerations (e.g., housing, transportation and access to outpatient facilities), must also be considered. Clear, proactive communication with patients and caregivers helps set expectations and confirms both feasibility and safety.

▲ **Remote Patient Monitoring:** The shift to outpatient care is only possible with robust RPM systems.[7,8] RPM allows for real-time or near real-time surveillance of patient status, enabling early detection and response to developing toxicities

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such as CRS or ICANS. Essential elements of RPM include:

- Wearable technology to continuously assess temperature, heart rate, respiratory rate, and oxygen saturation;[7]
- Scheduled virtual nurse or provider check-ins for symptom review, patient education, and ongoing risk assessment;[7]
- Standardized, protocols for escalation, including rapid intervention and seamless transfer to higher-acuity care if necessary;[7] and
- The capability for 24/7 virtual monitoring. This greatly enhances both patient safety and peace of mind for patients and caregivers.

Importantly, these tools provide comparable level of vigilance previously achieved in the inpatient setting, making outpatient care a safe alternative.[7] Careful selection of an RPM device company is important to ensure all these elements are achieved.

INFRASTRUCTURE AND LOGISTICS

Transitioning advanced therapies from the inpatient to outpatient setting requires thoughtful infrastructure redesign and close attention to logistics. At UCSF Health, these operational efforts were motivated both by a desire to improve patient experience and the need to repurpose acute care beds for the most ill and complex patients. Thus, freeing beds by moving lower-risk patients to outpatient or at-home settings became a central operational strategy.

A key component of this transition was the development of comprehensive standard operating procedures (SOPs) to ensure safety and clarity at each step. SOPs were created to serve as a framework for the new outpatient pathway, encompassing all major process points: patient education, scheduling, staff training, RPM device setup, configuration of alert thresholds, and defining the health system response and escalation pathways.

At UCSF Health, improving the patient experience has emerged as a key motivator for transitioning CAR T-cell and BTCE administration from the inpatient environment to outpatient clinics or even the home.

This meant that all team members, clinical and nonclinical, could consistently reference clear procedures for onboarding patients, deploying and configuring remote monitoring tools, addressing abnormal alerts, and facilitating coordinated care escalation if complications arose. Other critical requirements include:

- Infusion centers with adequate capacity, specially trained staff, and appropriate equipment for complex therapies and initial patient monitoring;[9]
- Direct access to emergency services and clearly delineated protocols for triage, urgent patient screening, and the expedited administration of critical rescue medications (e.g., tocilizumab for CRS);[9]
- Systems for after-hours coverage, including shared on-call arrangements and telehealth-based rapid assessment;[9]
- Mechanisms for urgent admission, including dedicated transition beds and established pathways for escalation from outpatient to inpatient care; and
- Support for temporary housing near the treatment center for patients who do not live locally, thus maintaining access to rapid intervention should symptoms arise.[9]

The implementation of SOPs across these domains fostered a reliable, stepwise process and reinforced the culture of safety and preparedness as the care setting shifted. This careful and deliberate reorganization of resources benefits not only patients receiving CAR T-cell and BTCE therapies, who have a more comfortable, less disruptive patient experience, but also enables institutions to better allocate complex inpatient care to those in critical need.

STAFF/PATIENT TRAINING AND EDUCATION

Comprehensive and ongoing staff education remains a cornerstone of outpatient therapy safety. To support the adoption of SOPs and other new protocols, education efforts focused on all involved personnel, including nurses, pharmacists, infusion center staff, emergency department clinicians and ancillary providers.

Staff training must routinely cover:

- Recognition and grading of CRS and ICANS in the outpatient setting;[10]
- Use of standardized pathways, including those detailed in the SOPs, for rescue therapy (e.g., tocilizumab prophylaxis and treatment for CRS, dexamethasone for ICANS and severe neurotoxicity);[9,10]
- Procedures for rapid admission, including both during and outside of regular hours;[9] and
- Reinforcement of interdisciplinary communication and continual protocol refinement in response to emerging best practices.[11]

The SOPs provided an essential educational tool during orientation and regular staff refreshers, supporting deliberate practice, simulations, and team-based audits to maintain high preparedness for the unique challenges of outpatient administration.

PATIENT/CAREGIVER EDUCATION AND SUPPORT

A fundamental component of effective RPM involves providing thorough patient education about the use, maintenance, and expectations of the monitoring devices. Clear, easy-to-understand instructions need to be shared with patients (and caregivers) in both verbal and written formats.

Education should include the following areas:

- During the initial setup, patients receive guidance on how to correctly place, activate and care for their RPM devices,

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such as wearables or transdermal patches. Demonstrations and supporting materials are provided to reinforce correct usage as needed.

▲ If a device becomes loose, falls off, or is damaged, patients should be instructed to promptly contact technical support using the provided number. Patients wearing the monitoring devices are instructed to inform the care team if they travel beyond the radius of the home hub that communicates the relevant metrics. When the patient comes back into range of the home hub, all metrics collected are populated automatically.

Patients are shown how to safely reapply the device or patch when appropriate, and backup devices or replacement instructions should be made readily available.

▲ Education on key health warning signs relevant to their monitored conditions, including abnormal heart rates, blood pressure spikes, or signs of infection. Materials clearly explain which symptoms or device alerts require switching between contacting the care team or seeking emergency assistance, such as calling 911.

▲ Encouragement to stay actively engaged is emphasized, promoting regular check-ins, understanding of their health data, and open communication by asking questions. A dedicated support hotline offers assistance for device-related inquiries as well as any health concerns tied to RPM data.

This structured, supportive approach aims not only to ensure compliance but also to empower patients as informed and active participants in managing their own health monitoring.

COST AND REIMBURSEMENT

A key consideration for shifting care out of the hospital is to reduce both direct and indirect healthcare costs. Prolonged inpatient admissions for therapy and monitoring greatly increase expenses, while outpatient care can lower overall costs, improve system efficiency, and make these therapies accessible to more patients.[12] Nevertheless, outpatient administration introduces different financial and logistical considerations.

For some patients, particularly those who live outside of a one-hour driving radius from the treatment center, it is necessary to arrange short-term housing nearby to ensure rapid access to the health system in case of urgent medical needs. The cost of hotel accommodation ("hoteling") or similar housing support should be factored into planning and budgeting for outpatient programs.

While these additional expenses are notable, financial modeling and institutional experience indicate that the avoidance of inpatient hospitalization days results in substantial cost savings that more than offset the costs associated with hoteling for most patients. Importantly, improving inpatient hospital throughput more than offsets the costs of implementing RPM.

In effect, the financial incentives to administer CAR T-cell therapies and BTCE in the outpatient setting, by reducing hospital bed utilization, lowering per-patient facility costs, and preventing hospital-acquired complications, are compelling from both payer and provider perspectives.

Importantly, the following reimbursement issues should be considered:

▲ Timely prior authorization for CAR T-cell and BTCE products and for essential rescue medications such as tocilizumab can be more challenging outside inpatient billing structures and should be proactively addressed.[12]

▲ Coverage policies for temporary housing or hoteling vary widely among commercial insurance plans; dedicated coordination and communication with payers are recommended to minimize patient financial burden.[12]

▲ The costs of RPM, including device setup, technical support, and ongoing clinical oversight, also carry reimbursement variability across payers.[7,12]

▲ Program investments in additional staffing, specialized training, and infrastructure must be weighed against the measurable reduction in inpatient utilization.[12]

Early and proactive engagement with payers, robust financial counseling for patients, and stakeholder collaboration are critical to the sustainability of outpatient CAR T-cell and BTCE programs. By carefully considering and planning for these factors, institutions can both enhance patient access and realize meaningful savings that support ongoing quality and innovation in care delivery.

STANDARDIZED TREATMENT PROTOCOLS

Clear, evidence-based protocols remain critical for high-quality outpatient care. These include standardized criteria for medication administration, early intervention for symptom development, and seamless integration of multidisciplinary expertise. For example:

▲ Early, protocol-driven administration of tocilizumab at the onset of CRS symptoms, rather than waiting for severity escalation in the outpatient context;[9]

▲ Use of dexamethasone for early neurotoxicity (ICANS) or, in selected programs, as prophylaxis;[9] and

▲ Clearly articulated referral or admission algorithms based on validated grading criteria and patient risk assessments.[9]

The SOPs codify these standardized approaches across patient care, ensuring consistency, safety, and collective clinical problem-solving, and enabling more patients to participate in outpatient or at-home treatment paradigms.

THE UCSF HEALTH EXPERIENCE

UCSF Health identified Current Health, Inc., as the preferred RPM provider based on three important elements:

1. The company's track record and experience in this space specifically supporting patients receiving CAR T-cell therapy;

2. The high level of direct patient technical support offered; and

3. The trained staff available to monitor

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patient metrics 24/7.

The rollout strategy began with a focus on BTCE and a gradual expansion to melphalan conditioning for autologous stem cell transplantation (ASCT) for multiple myeloma. The plan is to expand to CAR T-cell therapy as familiarity with the program grows.

The RPM program launched in October 2025. As of January 2026, four patients received talquetamab and one patient received teclistamab step-up dosing. One patient required admission unrelated to bispecific therapy for pain management issues. Most patients opted to stay at home, and one patient elected to stay in a nearby hotel. No cases of CRS or ICANS were observed in this small cohort.

Several patients were not eligible for outpatient therapy with reasons ranging from lack of patient reliability,[1] language barriers[1] and clinical challenges.[11] Examples of clinical challenges include significant disease burden, dementia, acute decompensation, significant cardiac issues and advanced kidney disease requiring dialysis.

Several important lessons were learned early on. The importance of reinforcing patient and caregiver responsibilities and ensuring understanding is essential.

Antipyretics and antipyretic ingredients in all medicines taken at home need to be avoided, especially those found in combination over-the-counter cough and cold medicines, as they can mask the emergence of CRS symptoms.

Simplifying documentation of patient and caregiver education as is a quality improvement step in the electronic medical record. The implementation of the outpatient immunotherapy program has resulted in 28 hospital days being saved in this small cohort.

The implementation of a program for just four patients has opened up valuable inpatient bed space better suited to manage the needs of acutely ill patients. The next step will be to evaluate prophylactic tocilizumab and characterize the patient's experience to understand its full impact on care, outcomes and quality of life.

CONCLUSION

The transition from inpatient to outpatient administration of advanced cancer immunotherapies represents a significant advance in patient care delivery. Outpatient and home-based models offer improved patient experience, greater autonomy, and reduced risk of hospital-acquired complications, while allowing healthcare systems to preserve precious inpatient resources for those most in need.

As demonstrated by UCSF Health and peer institutions, these aims can be realized safely through careful patient selection and education, investment in remote monitoring technology, comprehensive staff training, and implementation of detailed SOPs and standardized care protocols.

Sustainability of these models requires continued attention to reimbursement processes, patient access support, and iterative quality improvement based on accumulating real-world experience and outcomes data.

As the field expands, with more immunotherapies in the pipeline and more patients becoming candidates for these therapies, outpatient strategies are positioned to deliver efficient, innovative and compassionate care, benefiting both patients and the broader health system.

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REFERENCES

1. Maude SL, Laetsch TW, Buechner J, et al. Tisagenlecleucel in children and young adults with B-cell lymphoblastic leukemia. N Engl J Med. 2018;378(5):439-448. doi:10.1056/NEJMoa1709866.

2. Neelapu SS, Locke FL, Bartlett NL, et al. Axicabtagene ciloleucel CAR T-cell therapy in refractory large B-cell lymphoma. N Engl J Med. 2017;377(26):2531-2544. doi:10.1056/NEJMoa1707447.

3. June CH, Sadelain M. Chimeric antigen receptor therapy. N Engl J Med. 2018;379(1):64-73. doi:10.1056/NEJMra1706169.

4. Hossain N, Sahaf B, Abramian OG, et al. Outpatient administration of anti-CD19 CAR T cells for B-cell malignancies. J Clin Oncol. 2019;37(25):2130-2136. doi:10.1200/JCO.19.00429.

5. Shouse G, Guthrie K, Sanford D, et al. Implementation of an outpatient chimeric antigen receptor T-cell therapy program. JCO Oncol Pract. 2022;18(7):e1106-e1117. doi:10.1200/OP.21.00941.

6. Gutierrez C, McEvoy C, Munshi L, et al. Patient selection for outpatient chimeric antigen receptor T-cell therapy. Blood Adv. 2023;7(12):3500-3506. doi:10.1182/bloodadvances.2023010504.

7. Hanley PJ, Orgel E, Bhatt N, et al. Remote patient monitoring in outpatient CAR T-cell therapy: Harnessing digital health for improved outcomes. J Clin Med. 2022;11(14):4036. doi:10.3390/jcm11144036.

8. Dahi PB, Sauter CS, Hirsel J, et al. Outpatient chimeric antigen receptor T-cell therapy using remote patient monitoring. Blood Adv. 2023;7(9):2190-2198. doi:10.1182/bloodadvances.2022009437.

9. Chong EA, Svoboda J, Nasta SD, et al. Outpatient management following CAR T-cell therapy. J Oncol Pract. 2020;16(2):90-95. doi:10.1200/JOP.19.00507.

10. Lee DW, Santomasso BD, Locke FL, et al. ASTCT consensus grading for cytokine release syndrome and neurologic toxicity associated with immune effector cells. Biol Blood Marrow Transplant. 2019;25(4):625-638. doi:10.1016/j.bbmt.2018.12.758.

11. Karschnia P, Holtzman NG, Bouffard DA, et al. Staff education in immunotherapy toxicities: Protocol development and implementation. Oncologist. 2020;25(6):e1080-e1087. doi:10.1634/theoncologist.2019-0894.

12. Hausman N, Choi J, Longo W, et al. Outpatient CAR T-cell therapy: Cost analysis and reimbursement landscape. Am J Manag Care. 2023;29(2):e47-e54. doi:10.37765/ajmc.2023.89212.