THE BIG PICTURE

Outpatient CAR T-Cell Therapy: Same powerful therapy. A different care model.

What it is, why it matters, and what clinics must solve to deliver it safely

1 The One Thing to Know



What "outpatient CAR T-cell therapy" actually means



Why outpatient CAR T-cell therapy matters



The challenges clinics must solve



What a strong outpatient program looks like



Quick Myth Check

1 The One Thing to Know



THE ONE THING TO KNOW
Outpatient does not mean low risk.
It means CAR T-cell infusion, early monitoring, or both occur outside a hospital bed—with specialized staff, product- and protocol-specific evaluation, a prepared caregiver, 24/7 access to the CAR T-cell team, and a rapid path to hospital care when needed.

Why now

Use of chimeric antigen receptor (CAR) T-cell therapy is expanding. Inpatient beds are limited, and programs have greater experience recognizing and managing cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). Together, these factors support outpatient care for carefully selected patients.[1-3]

In 2025, the U.S. Food and Drug Administration (FDA) eliminated Risk Evaluation and Mitigation Strategies (REMS) for six autologous CAR T-cell products previously subject to REMS, reducing regulatory burden while retaining product-specific safety requirements.[4] FDA also revised affected labels to require monitoring for at least 2 weeks, including daily monitoring for at least 1 week, and proximity to a healthcare facility for at least 2 weeks.

In 30 seconds

- The patient may receive CAR T cells in an outpatient clinic or day hospital.
- The patient generally remains near the treatment center with a trained caregiver and returns for product- and protocol-specific assessments.
- The team watches closely for CRS, ICANS, infection, cytopenias, and other complications.
- If risk rises, the patient is evaluated promptly, treatment is initiated when indicated, and hospital admission or transfer occurs without avoidable delay.

What "outpatient CAR T-cell therapy" actually means



THE MODEL
A planned ambulatory pathway—not a promise to avoid hospitalization.
Programs differ. Some provide outpatient infusion and monitoring; others admit only if toxicity develops. Monitoring may combine clinic visits, caregiver checks, phone or telehealth contact, or remote monitoring devices. Requirements remain product specific.

The care journey

1. SELECT	The team evaluates clinical risk, product, disease, comorbidities, performance status, cognition, caregiver readiness, lodging, travel time, and transportation.
2. PREPARE	The patient and caregiver learn what to monitor, when to call, and where to go. Staff test emergency, transfer, and admission workflows.
3. INFUSE	CAR T cells are administered in an equipped outpatient setting with trained staff and required toxicity-management and emergency medications available.
4. MONITOR	The patient remains within required proximity and completes product- and protocol-specific monitoring during the early post-infusion period.
5. ESCALATE	Signs of possible toxicity trigger immediate assessment and treatment, with admission or ICU transfer when indicated.
6. REVIEW	The program reviews every early case, including response times, admissions, deviations, and patient/caregiver experience.

A critical nuance

Hospitalization remains common. In one outpatient cohort, 42 of 58 patients (72%) were admitted within 30 days, most often for CAR T-cell-related toxicity. Outpatient delivery nevertheless reduced hospital days versus a historical inpatient cohort, and selected low-grade toxicities were managed without admission.[5]

BOTTOM LINE
Admission is not automatically a program failure.
A fast, appropriate admission can be evidence that the safety system worked. The better questions are:
Was toxicity recognized early? Was treatment prompt?
Did the transfer work? Was the patient kept safe?

Why outpatient CAR T-cell therapy matters



THE OPPORTUNITY
Use the right setting for the right patient at the right time.
Outpatient care can reduce planned inpatient time for selected patients while preserving rapid access to inpatient and intensive care when needed.

Potential advantages

- **For patients:** More time outside the hospital, greater familiarity and autonomy, potentially less deconditioning, and fewer disruptions from prolonged inpatient stays.
- **For caregivers:** More involvement and visibility—but only when responsibilities and support are realistic.
- **For clinics:** Better use of beds and clinical space, more flexible capacity, and a pathway to expand access.
- **For health systems:** Fewer planned inpatient days, possible reductions in resource use, and more efficient deployment of specialized teams.
- **For the field:** Greater potential to bring CAR T-cell therapy closer to patients, including through capable community-based programs and partnerships.

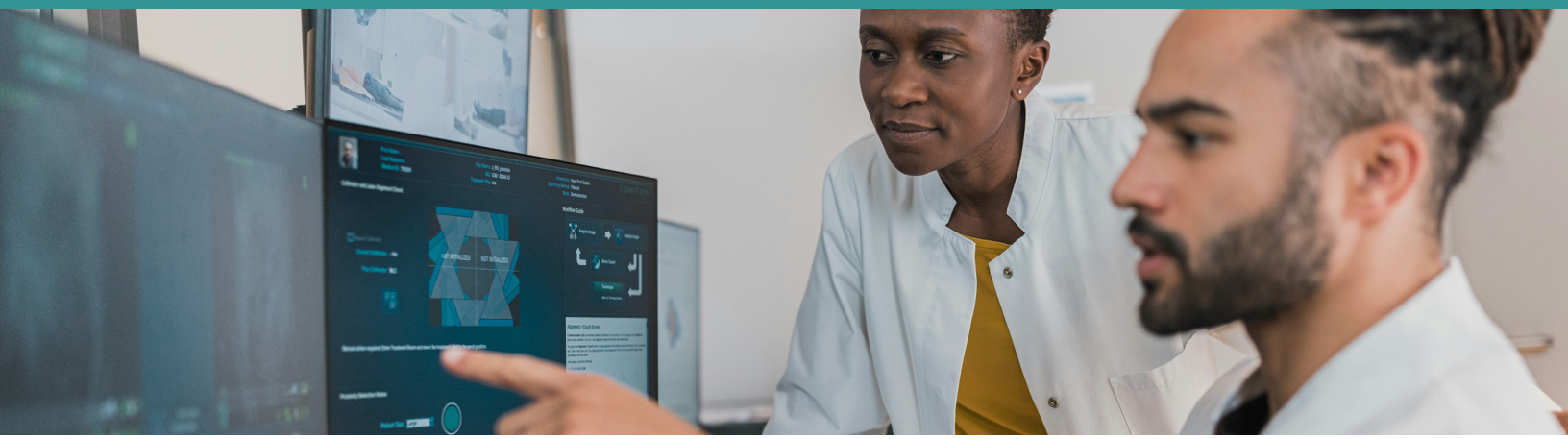
Published reviews identify access, bed capacity, patient experience, and resource utilization as key reasons to consider outpatient models; newer real-world reports also demonstrate feasibility in selected community-based programs.[1-3,6,7]

What the evidence suggests

FEASIBLE	Multiple centers have reported that outpatient administration is feasible with selected commercial products and patient populations.
NOT ONE-SIZE-FITS-ALL	Toxicity timing and profile, disease burden, patient condition, caregiver capacity, and center infrastructure must shape the setting.
EARLY ACTION MATTERS	Programs need rapid evaluation and ready access to tocilizumab, corticosteroids, antimicrobials, and other supportive care when clinically indicated, in accordance with current prescribing information and institutional protocols.
SYSTEM DESIGN MATTERS	Safety depends on the whole pathway—clinic, caregiver, pharmacy, laboratory, ED, hospital, ICU, transport, social work, and finance—not the infusion chair alone.

THE STRATEGIC VALUE
Outpatient CAR T-cell therapy can expand capacity without lowering the safety bar.
The goal is not to keep every patient out of the hospital. The goal is to avoid hospitalization when it is unnecessary—and make hospital care immediate when it becomes necessary.

The challenges clinics must solve



REALITY CHECK
The infusion is the easy part.
The hardest work happens before and after it: selecting the right patient, preparing the caregiver, ensuring monitoring coverage, recognizing toxicity early, and moving a deteriorating patient safely.

1. Safety and toxicity

- CRS, ICANS, infection, cytopenias, and other complications may evolve quickly.
- Fever may reflect CRS, infection, or both. Teams must avoid diagnostic anchoring.
- Programs need clear toxicity-management, hospital-admission, and intensive care unit (ICU) transfer criteria, with required medications and supportive care available without avoidable delay.

2. Patient and caregiver demands

- The patient must meet product-specific proximity requirements and any additional institutional criteria during the early post-infusion period.
- Depending on the product, patient, and program, a reliable caregiver may need to provide continuous presence, monitoring, transportation, medication support, and urgent communication.
- Language, health literacy, disability, digital access, lodging, food, employment, and caregiver fatigue can determine whether outpatient care is truly safe and equitable.

3. Operational readiness

- Programs need monitoring access that meets product labeling and institutional protocols, including on weekends and holidays when needed.
- A clinician trained in CAR T-cell toxicity management should be available 24/7.
- Programs need rapid access to laboratory testing, transfusion support, pharmacy, imaging, transport, the emergency department (ED), direct admission, and ICU care.
- Programs need validated processes for cell handling, chain of identity, chain of custody, handoffs, and downtime, as well as appropriate electronic health record (EHR) tools.

4. Financial uncertainty

- Outpatient authorization and reimbursement vary by payer.
- A later inpatient admission can change coding, contracting, and financial exposure.
- Drug acquisition, denials, lodging, caregiver costs, and uncompensated monitoring can threaten sustainability.

These clinical, operational, caregiver, and financial barriers recur across expert recommendations, implementation reviews, and community experience.[1-3,6-9]

5. Quality and accreditation

- Align program policies, competencies, chain-of-identity/custody processes, and quality oversight with applicable FACT IEC standards, manufacturer requirements, and institutional policies.

What a strong outpatient program looks like



THE STANDARD
Built for the worst plausible day—not the average day.
A safe program can recognize deterioration at 2 p.m. or 2 a.m., initiate the appropriate response, and move the patient to the right level of care without improvisation.

The essentials

- **Select deliberately:** Written eligibility criteria integrate clinical risk, product, disease, performance status, organ function, cognition, caregiver readiness, distance, lodging, transportation, and psychosocial factors.
- **Train for action:** Prepare patients, caregivers, and participating teams—including clinic staff, ED, ICU, pharmacy, laboratory, social work, and transport—for their roles.
- **Monitor reliably:** Every required assessment has a frequency, owner, alert threshold, review expectation, escalation pathway, and backup plan.
- **Treat early:** Toxicity-management medications and supportive care are available without avoidable delay, and institutionally approved order sets align with current prescribing information and institutional protocols.
- **Escalate without friction:** Direct-admission or ED pathways specify who accepts the patient, where the patient goes, how transport occurs, and what happens if the preferred bed or level of care is unavailable.
- **Measure what matters:** Programs track toxicity, admissions, ED and ICU use, treatment and transfer times, deviations, patient and caregiver experience, equity, cost, reimbursement, and denials.
- **Consider a staged launch:** A defined pilot, enhanced oversight, case-by-case review, and predetermined pause or stop criteria can help the program learn before expanding.[2]

Three questions leaders should ask

- Can we identify the right patients—and say no when outpatient care is not safe?
- Can we deliver the same urgency at night, on weekends, and when the hospital is full?
- Can we prove the model is safe, equitable, operationally reliable, and financially sustainable?

THE TAKEAWAY
Outpatient CAR T-cell therapy is not less care.
It is care organized differently: more preparation, more coordination, and greater reliance on rapid recognition and response. When those systems are strong, outpatient delivery can improve capacity and patient experience while maintaining a clear path to hospital care.

Quick Myth Check



MYTH: Outpatient means the patient will not be admitted.	REALITY: Many patients still require admission. The outpatient model determines where care starts—not where every patient will finish.
MYTH: A wearable device makes outpatient care safe.	REALITY: Technology can add data, but it cannot replace trained caregivers, clinical judgment, reliable response, or hospital access.
MYTH: Lower admission rates always mean better performance.	REALITY: Delayed or avoided admission can be unsafe. Interpret utilization with toxicity severity, response time, outcomes, and case mix.
MYTH: Any stable patient can be treated outpatient.	REALITY: Eligibility is dynamic and includes disease and product factors, performance status, comorbidities, cognition, caregiver readiness, lodging, transportation, and center capability.
MYTH: Outpatient care simply shifts cost out of the hospital.	REALITY: Financial impact depends on payer policy, contracts, drug acquisition, monitoring, denials, and later inpatient care.
MYTH: The CAR T-cell team can manage the program alone.	REALITY: Safe delivery requires coordinated clinic, pharmacy, laboratory, ED, ICU, inpatient, transport, quality, social work, and finance partners.

References

1. Gatwood K, Mahmoudjafari Z, Baer B, et al. Outpatient CAR T-cell therapy as standard of care: current perspectives and considerations. *Clin Hematol Int.* 2024;6(2):11-20. doi:10.46989/001c.115793

2. Oluwole OO, Dholaria B, Knight TE, et al. Chimeric antigen receptor T-cell therapy in the outpatient setting: an expert panel opinion from the American Society for Transplantation and Cellular Therapy. *Transplant Cell Ther.* 2024;30(2):131-142. doi:10.1016/j.jtct.2023.11.008

3. Perez A, Al Sagheer T, Nahas GR, Linhares YPL. Outpatient administration of CAR T-cell therapy: a focused review with recommendations for implementation in community-based centers. *Front Immunol.* 2024;15:1412002. doi:10.3389/fimmu.2024.1412002

4. US Food and Drug Administration. FDA eliminates Risk Evaluation and Mitigation Strategies (REMS) for autologous chimeric antigen receptor (CAR) T cell immunotherapies. Published June 26, 2025. Accessed September 4, 2026. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor

5. Furqan F, Bhatlapenumarthi V, Dhakal B, et al. Outpatient administration of CAR T-cell therapies using a strategy of no remote monitoring and early CRS intervention. *Blood Adv.* 2024;8(16):4320-4329. doi:10.1182/bloodadvances.2024013239

6. Association of Cancer Care Centers Immuno-Oncology Institute. CAR T-cell therapy in action: successful examples in outpatient settings. Accessed September 4, 2026. https://www.accc-cancer.org/docs/projects/car-t-cell-therapies/car-t-cell-therapy-in-action---successful-examples-in-outpatient-settings.pdf

7. Simmons GL, Cross S, Pittos EC. Advancing access to CAR T-cell therapy: insights and real-world experience from a community oncology practice. *Front Oncol.* 2026;16:1712533. doi:10.3389/fonc.2026.1712533

8. Alsina M, Dhakal B, Pantin J, Huff CA, Janakiram M. Establishing a successful outpatient CAR T-cell program with cilta-cel: real-world experience from an expert roundtable. *Future Oncol.* 2025;21(10):1137-1144. doi:10.1080/14796694.2025.2476382

9. Immune Effector Standards. Foundation for the Accreditation of Cellular Therapy. Accessed September 9, 2026. https://consulting.factglobal.org/standards/immune-effector-standards

IMPORTANT NOTICE: The NCODA Immunotherapy Hub and its associated resources are provided for general educational and informational purposes only. They do not constitute medical advice, diagnosis, treatment, prescribing guidance, or a standard of care; are not a substitute for independent professional judgment; and do not create a healthcare professional-patient or other professional relationship with NCODA or its employees, authors, reviewers, contributors, collaborators, or affiliated organizations.

NCODA makes reasonable efforts to provide accurate and current information; however, these resources may not include all available information regarding medications, treatments, or clinical practices, including indications, dosing, administration, contraindications, precautions, warnings, interactions, adverse reactions, monitoring, or other risks. Medical evidence, regulatory requirements, product labeling, and clinical guidelines may change after publication. Healthcare professionals are responsible for independently verifying information against current FDA-approved prescribing information, applicable clinical guidelines, institutional policies, and other authoritative sources and for exercising independent clinical judgment when making patient-care decisions.

The resources are provided “as is” and, to the fullest extent permitted by applicable law, NCODA makes no warranties regarding their completeness, accuracy, reliability, applicability, or timeliness. Reference to any medication, manufacturer, product, service, treatment, organization, or third-party resource does not constitute or imply endorsement or recommendation by NCODA. NCODA is not responsible for the content, accuracy, availability, or practices of third-party resources referenced or linked within the Immunotherapy Hub.

To the fullest extent permitted by applicable law, NCODA and its officers, directors, employees, contractors, authors, reviewers, contributors, collaborators, sponsors, and affiliated organizations disclaim liability for any claim, loss, injury, damage, cost, or expense arising from or related to the use, misuse, interpretation of, inability to use, or reliance upon these resources, including information contained in or omitted from them. Nothing in this disclaimer excludes or limits liability that cannot lawfully be excluded or limited.

Patients and caregivers should not use these resources to diagnose a condition or initiate, discontinue, or change treatment without consulting a qualified healthcare professional and should never disregard or delay professional medical advice because of information contained in the Immunotherapy Hub. These resources are not intended for medical emergencies; individuals experiencing a medical emergency should seek immediate medical assistance.