

Outpatient CAR-T Patient and Caregiver Eligibility, Education, and Monitoring Toolkit

A coordinated set of clinic forms, competency checks, home-monitoring tools, and escalation instructions

PURPOSE

Support consistent outpatient candidate selection, caregiver preparation, post-infusion monitoring, and rapid response to emerging toxicity. Use only after adaptation and approval by the treating institution.

Toolkit components

- Multidisciplinary outpatient eligibility assessment and final disposition
- Caregiver readiness assessment, education checklist, and competency validation
- Patient and caregiver plain-language action plan
- Daily monitoring record and structured clinical follow-up form
- Exception, reassessment, and escalation documentation

Development basis

The framework synthesizes expert recommendations, implementation reviews, a contemporary outpatient cohort, and community program examples. Practice insights were also informed by interviews with thought leaders.

How to Use This Toolkit

Successful outpatient care depends on more than clinical stability. Selection should also account for product toxicity, disease characteristics, caregiver capability, proximity, transportation, communication, psychosocial needs, and the center's ability to intervene rapidly.^{1-3,5}

Recommended workflow

1. Screen for potential outpatient eligibility before lymphodepletion, allowing time to resolve logistical or caregiver barriers.
2. Complete multidisciplinary clinical, psychosocial, logistical, caregiver, and financial assessments.
3. Confirm the final setting shortly before infusion because disease status, organ function, caregiver availability, and lodging may change.
4. Validate patient and caregiver competency using teach-back and return demonstration.
5. Provide the institution-approved action plan, contact routes, monitoring equipment, and written schedule.
6. Reassess eligibility daily during the high-risk monitoring period; convert to inpatient care when safety conditions are no longer met.

CLINICAL JUDGMENT AND CURRENT REQUIREMENTS

This toolkit does not establish universal cutoffs for age, distance, vital signs, laboratory results, disease burden, monitoring frequency, or duration. Populate local thresholds from current product labeling, evidence, and institution-approved policies. For the six autologous CD19- and BCMA-directed products covered by FDA's June 2025 action, REMS requirements were eliminated and product labeling was updated; use current product-specific labeling rather than legacy REMS workflows.⁶ Programs should also align local policies with applicable FACT IEC standards, including the 2025 Community IEC Standards when relevant.⁷

Decision categories

Disposition	Meaning	Required action
Eligible	All required criteria met; residual risks acceptable.	Proceed with outpatient plan and document final verification.
Conditionally eligible	One or more remediable barriers or enhanced-monitoring needs.	Document mitigation, owner, completion deadline, and approval.
Not currently eligible	Safety requirement not met or risk exceeds outpatient capability.	Use inpatient plan; reassess if circumstances change.
Outpatient plan discontinued	Previously eligible patient no longer meets criteria.	Activate escalation/admission pathway and document reason.

Form 1. Outpatient Eligibility Assessment

Patient information	Entry
Patient name / MRN	
Diagnosis / disease status	
CAR-T product / target	
Planned infusion date / location	
Primary oncologist / cellular therapy physician	
Primary caregiver / backup caregiver	
Local lodging address / travel time	
Assessment date / reassessment date	
Assessors and disciplines represented	

A. Clinical and treatment-related assessment

ID	Criterion	Met	Not met	N/A	Evidence / mitigation
A1	Product- and indication-specific outpatient requirements reviewed.				
A2	Disease burden, tempo, and expected toxicity risk are acceptable for the planned monitoring model.				
A3	Performance and functional status support safe outpatient care.				
A4	Cardiovascular, pulmonary, renal, hepatic, and neurologic status are acceptable or have an approved mitigation plan.				
A5	No uncontrolled infection or other acute condition requiring inpatient management.				
A6	Baseline cognition, communication, handwriting, and ICE or age-/developmentally appropriate neurologic assessment (e.g., CAPD), when applicable.				
A7	Baseline vital signs, laboratory values, and relevant diagnostics meet local criteria.				
A8	Lymphodepletion plan, supportive medications, and timing are compatible with outpatient care.				
A9	Potential interactions, sedating medications, and medications that may obscure toxicity have been reviewed.				
A10	Patient can take oral medications and maintain hydration/nutrition or has a safe support plan.				

Form 1. Eligibility Assessment—Continued

B. Psychosocial, cognitive, and behavioral assessment

ID	Criterion	Met	Not met	N/A	Evidence / mitigation
B1	Patient understands outpatient responsibilities and agrees with the plan.				
B2	Patient can recognize and communicate symptoms or has continuous caregiver support that compensates.				
B3	Mental health, substance use, delirium risk, and behavioral concerns are stable or appropriately supported.				
B4	Language, health literacy, vision, hearing, mobility, and disability needs are addressed.				
B5	Patient has reliable access to required phone/communication methods.				
B6	Patient and caregiver can follow the monitoring schedule and attend all visits.				

C. Logistics, proximity, and access assessment

ID	Criterion	Met	Not met	N/A	Evidence / mitigation
C1	Local lodging meets institution-defined travel-time requirements for the full required period.				
C2	Reliable primary transportation and backup transportation are confirmed.				
C3	Patient and caregiver know the clinic, after-hours, emergency, and transfer destinations.				
C4	Financial authorization/site-of-care review is complete.				
C5	Lodging, food, parking, employment, dependent-care, and other practical barriers have been assessed.				
C6	A plan exists for equipment failure, phone outage, severe weather, or transportation disruption.				

Form 1. Eligibility Decision and Reassessment

D. Required caregiver and monitoring capabilities

ID	Criterion	Met	Not met	N/A	Evidence / mitigation
D1	Qualified primary caregiver is available for the institution-defined period.				
D2	Backup caregiver is identified and trained when required.				
D3	Caregiver can remain with the patient and provide reliable transport.				
D4	Caregiver can use monitoring equipment and accurately record results.				
D5	Caregiver can perform or assist with neurologic/ICE checks when required.				
D6	Caregiver can identify red-flag symptoms and activate the correct response without delay.				
D7	Patient/caregiver teach-back and return demonstration are complete.				
D8	Clinical team can review monitoring data and respond at all required times.				

Final disposition

Decision	Selection	Rationale / required mitigation
Eligible	☐	
Conditionally eligible	☐	
Not currently eligible	☐	
Outpatient plan discontinued	☐	

Approval role	Name	Signature / date
Cellular therapy physician		
APP / nursing		
Pharmacist		
Social work / case management		
Program designee		

DAILY SAFETY REASSESSMENT

Eligibility is dynamic. Reassess clinical status, caregiver availability, lodging, transportation, communication, and monitoring reliability at each high-risk encounter and whenever circumstances change.

Form 2. Caregiver Readiness Assessment

Recommendations emphasize a qualified caregiver who can remain with the patient, recognize toxicity, communicate promptly, provide transportation, and use monitoring tools as required.^{1-3,5}

Caregiver information	Entry
Primary caregiver / relationship	
Backup caregiver / relationship	
Preferred language / interpreter needs	
Phone(s) / alternative contact	
Availability dates and hours	
Driver / vehicle / transportation backup	
Other caregiving, work, health, or accessibility needs	

Capability	Independent	Needs support	Not demonstrated	Comments / plan
States the purpose of outpatient monitoring and agrees to remain available as required.				
Names the 24/7 contact number and demonstrates how to reach the CAR-T team.				
Explains which symptoms require an immediate call and which require 911/emergency response.				
Measures and records temperature correctly.				
Measures and records blood pressure, pulse, and oxygen saturation when required.				
Performs or assists with ICE/neurologic assessment when required.				
Manages the medication list and identifies prohibited or as-needed medications requiring team guidance.				
Describes the daily visit and monitoring schedule.				
States lodging and travel-time requirements and can describe primary/backup transportation.				
Can provide concise handoff information: product, infusion date, symptoms, vital signs, and recent interventions.				
Identifies fatigue, stress, health, language, literacy, or digital barriers that could impair caregiving.				
Knows how and when to activate the backup caregiver.				

Form 3. Education and Competency Checklist

Topic	Required content	Educator / date	Teach-back passed	Re-teach / follow-up
Treatment overview	Purpose of CAR-T therapy; lymphodepletion, infusion, and follow-up sequence.			
Expected symptoms	Fatigue, appetite changes, cytopenias, infection risk, and product/institution-specific expectations.			
CRS	Fever and associated symptoms; urgency of reporting; do not self-treat fever unless instructed.			
ICANS / neurologic changes	Confusion, difficulty speaking/writing, tremor, weakness, severe headache, seizure, or altered alertness.			
Other serious/product-specific toxicities and delayed adverse effects	Product- and timing-specific risks (e.g., IEC-HS [HLH/MAS-like hyperinflammation], delayed/non-ICANS neurologic toxicities, and IEC-associated enterocolitis with cilta-cel when applicable); warning signs and when to call. ⁸			
Infection and other emergencies	Fever, chills, bleeding, chest pain, severe dyspnea, syncope, or other locally defined red flags.			
Monitoring	Equipment, frequency, technique, thresholds, logging, and who reviews the results.			
Medications	Current list, supportive medicines, restrictions, and whom to call before starting new drugs.			
Safety restrictions	Driving, machinery, alcohol/substances, and product-specific restrictions from current instructions.			
Visits and proximity	Daily/required visits, local lodging, travel-time rule, and duration.			
Communication	24/7 number, portal limitations, backup numbers, 911 instructions, and what information to provide.			
Escalation and admission	Where to go, transport method, direct admission vs ED, and what to bring.			
Caregiver wellness	Rest, backup coverage, food, lodging, employment, and when to disclose inability to continue.			

Competency validation

Return demonstration	Patient	Primary caregiver	Backup caregiver	Validated by / date
Temperature				
Blood pressure / pulse				
Pulse oximetry				
ICE / neurologic check, if used				
Monitoring log				
Calling 24/7 line and giving handoff				

Patient and Caregiver Action Plan

KEEP THIS PAGE VISIBLE

Bring it to every clinic or emergency visit. Complete all blanks before discharge from the infusion visit. The treating program must replace the examples below with its approved thresholds and instructions.

Your CAR-T information	Write in
Patient name / MRN	
CAR-T product / infusion date	
Treating center / physician	
Local lodging address	
Primary caregiver / phone	
Backup caregiver / phone	
24/7 CAR-T number	
Emergency destination / address	
Transport plan / backup	

Call the CAR-T team immediately

- Temperature at or above the threshold provided by your center: _____
- New confusion, trouble speaking, trouble writing, unusual sleepiness, tremor, weakness, imbalance, or severe headache
- New shortness of breath, dizziness, faintness, fast heartbeat, low blood pressure, or low oxygen reading
- Chills, new or worsening nausea/vomiting/diarrhea, inability to drink or take medicines, new rash, bleeding, or any rapid change
- Any monitor alert or measurement outside the limits your team gave you
- If either the patient or caregiver is unsure whether a symptom is important

Call 911 now

- Seizure, loss of consciousness, inability to awaken, or sudden severe neurologic change
- Severe trouble breathing, blue/gray lips, severe chest pain, or collapse
- Any situation that appears immediately life-threatening

DO NOT DELAY

Do not wait for the next clinic visit or send only a portal message for urgent symptoms. Do not take acetaminophen or another fever-reducing medicine that can mask a fever unless the CAR-T team instructs you to do so.

What to Say When You Call

Use this script

CALL HANDOFF

“I am calling about _____, who received _____ CAR-T cells on _____. The current concern is _____. Symptoms began at _____. Current temperature is _____; blood pressure _____/_____; pulse _____; oxygen ____%. The most recent neurologic/ICE result is _____. We have/have not given any medication. We are currently at _____ and can reach the center in approximately _____ minutes.”

Before leaving for evaluation

- Follow the CAR-T team's destination and transport instructions.
- Bring the CAR-T identification/wallet card, current medication list, action plan, and monitoring log.
- Do not allow the patient to drive.
- If calling 911, tell responders that the patient recently received CAR-T therapy and may have CRS or neurologic toxicity.
- If the patient's condition worsens while traveling, call 911.

Your center's specific instructions

Situation	Who to call	Where to go	Transport	Special instruction
Clinic hours				
After hours				
Immediate emergency				
No answer / failed connection				
Severe weather / transport failure				

Home Monitoring Plan

Published outpatient models vary: some use home monitoring and frequent caregiver checks, whereas others use daily center visits without intensive remote monitoring. The selected model must be deliberate, reliable, and matched to institutional response capability.^{1,2,4}

Monitoring element	Local plan
Required period / dates	From _____ through _____
In-person visit frequency	
Home-check frequency and times	
Temperature method / alert threshold	
Blood pressure / pulse method and thresholds	
Oxygen saturation method and threshold	
ICE / neurologic assessment and threshold	
Symptom questionnaire / portal / phone process	
Who reviews data and by what time	
What to do if data are not transmitted	
Equipment support / replacement number	
24/7 escalation number	

Equipment issue plan

Problem	Immediate action	Contact / backup
Thermometer unavailable or inconsistent		
BP cuff error / wrong size		
Pulse oximeter poor signal		
Remote device / app offline		
Phone or internet outage		
Unable to complete neurologic check		

Daily Home Monitoring Record

Patient: _____ Product: _____ Infusion date: _____ Day after infusion: _____ Date: _____

Time	Temp	BP	Pulse	O ₂ sat	ICE / neuro result	Symptoms / changes	Action taken / call time	Team instruction
Morning _____								
Midday _____								
Evening _____								
Night _____								
Extra check _____								
Extra check _____								

Symptoms to actively check

Fever / chills	Confusion / speech	Writing change	Tremor / weakness	Headache	Breathing / dizziness	GI / intake	Other
☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	
☐	☐	☐	☐	☐	☐	☐	

ANY CONCERNING CHANGE?

Follow your action plan and call the CAR-T team immediately. Do not wait to finish the log.

Clinical Follow-Up and Reassessment

Visit information	Entry
Date / day after infusion / location	
Patient and caregiver present	
Interval calls, alerts, ED visits, or admissions	
Medication changes / interventions	
Data reviewed from home monitoring	
New logistical or caregiver concern	

Assessment element	Complete	Finding / action
Vital signs and weight reviewed.		
CRS grade and supporting findings documented.		
ICE score / ICANS grade and neurologic findings documented.		
Other serious/product-specific toxicities and delayed adverse effects assessed as applicable (e.g., IEC-HS [HLH/MAS-like hyperinflammation], delayed/non-ICANS neurologic toxicities, IEC-associated enterocolitis).		
Infection symptoms and antimicrobial needs assessed.		
CBC, chemistry, and other required results reviewed.		
Hydration, nutrition, medications, and supportive care assessed.		
Caregiver availability and performance remain adequate.		
Lodging, transportation, communication, and equipment remain reliable.		
Patient remains appropriate for outpatient monitoring.		

Disposition	Select	Plan
Continue outpatient monitoring	☐	
Continue with enhanced monitoring	☐	
Urgent evaluation / treatment	☐	
Admit / transfer	☐	
Other	☐	

Exception and Reassessment Form

USE FOR ANY UNMET CRITERION

An exception should never be implied by proceeding. Document the exact criterion, clinical and operational risk, mitigation, monitoring change, approving authority, expiration, and reassessment trigger.

Exception element	Documentation
Eligibility criterion / requirement not met	
Reason / new circumstance	
Patient-safety and operational risk	
Mitigation and enhanced monitoring	
Responsible owner and completion date	
Duration / expiration	
Trigger for immediate inpatient conversion	
Patient/caregiver discussion and agreement	
Approvals / signatures	
Final disposition	Eligible / Conditionally eligible / Not currently eligible/ Outpatient plan discontinued

Barrier-resolution tracker

Barrier	Action	Owner	Due	Resolved / evidence

Program Quality Checks

Audit a sample of patient/caregiver records for completeness and performance.

Domain	Audit question	Numerator / denominator	Target	Result / action
Eligibility	Eligibility and final preinfusion reassessment completed before outpatient infusion.			
Caregiver	Primary/backup caregiver requirements and competency documented.			
Education	Teach-back and return demonstrations passed before infusion.			
Monitoring	Expected checks completed and reviewed within the defined timeframe.			
Escalation	Concerning symptoms reached the correct clinician without avoidable delay.			
Access	Lodging, transport, language, digital, or financial barriers were addressed.			
Conversion	Reasons for ED visit/admission and timing were documented.			
Experience	Patient and caregiver burden, confidence, and satisfaction were assessed.			
Equity	Eligibility and outpatient completion were reviewed across relevant populations.			

Patient/caregiver debrief prompts

- Did you know what to monitor and when to call?
- Could you reach the team quickly at all hours?
- Were lodging and transportation manageable?
- Which instructions or tools were confusing?
- Did the caregiver have adequate rest and backup?
- What would have made outpatient care feel safer or easier?

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. Furqan F, Bhatlapenumarthy 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
5. Association of Cancer Care Centers. CAR T-Cell Therapy in Action: Successful Examples in Outpatient Settings. Association of Cancer Care Centers; 2024.
6. US Food and Drug Administration. FDA eliminates Risk Evaluation and Mitigation Strategies (REMS) for autologous chimeric antigen receptor (CAR) T cell immunotherapies. Published June 27, 2025. Accessed September 14, 2026. <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor>
7. Foundation for the Accreditation of Cellular Therapy. Standards for Immune Effector Cells in the Community Clinical Setting. 1st ed. Published November 10, 2025. Accessed September 14, 2026. <https://consulting.factglobal.org/standards/immune-effector-standards/>
8. Perales MA, Dietrich J, Gust J, et al. ASTCT consensus grading for toxicities after immune effector cell therapy. *Transplant Cell Ther*. Published online September 8, 2026. doi:10.1016/j.jtct.2026.05.020

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