

Outpatient CAR-T Toxicity and Rapid-Escalation Playbook

Role-based workflows for recognition, stabilization, treatment, transport, admission, and clinical handoff

PURPOSE

Convert outpatient CAR-T emergency plans into executable workflows across clinic hours, after hours, transport, the emergency department, direct admission, and intensive care. This playbook must be localized and approved before use. It supports, but does not replace, current product labeling, applicable FDA/regulatory requirements, FACT/accreditation standards, or institutional policies.

Core operating principle

Outpatient CAR-T safety depends on early toxicity recognition, immediate access to trained clinicians, timely supportive and immunomodulatory treatment, and a reliable pathway to higher-level care.¹⁻⁴

Playbook contents

- Activation criteria and role assignments
- First-call triage and syndrome-specific response pathways
- In-hours, after-hours, ED, direct-admission, ICU, and transport workflows
- Medication and operational readiness checks
- Handoff, downtime, simulation, event review, and quality metrics

How to Localize and Use This Playbook

REQUIRED BEFORE GO-LIVE

Replace every blank, role label, phone number, destination, clinical threshold, medication instruction, and response target with institution-approved content. Verify current product labeling, applicable FDA/regulatory requirements, toxicity-management guidance, FACT/accreditation standards, and local emergency policies.^{5,6}

Activation triggers

Trigger group	Examples requiring immediate assessment
Possible CRS	Fever or locally defined temperature alert; chills; hypotension; hypoxia; tachycardia; malaise; rapid clinical change.
Possible ICANS	New confusion, impaired attention, speech or writing change, tremor, weakness, somnolence, seizure, or reduced consciousness.
Possible infection/sepsis	Fever, rigors, focal infection symptoms, hypotension, hypoxia, or organ dysfunction—alone or concurrent with CRS.
Other serious / product-specific toxicity	Persistent or recurrent hyperinflammation after CRS; rapidly rising ferritin with cytopenias, coagulopathy, or organ dysfunction; delayed/non-ICANS neurologic change; severe or prolonged diarrhea, abdominal pain, or weight loss after a product associated with IEC-enterocolitis; or another serious toxicity identified in current product labeling.
Other emergency	Chest pain, severe dyspnea, syncope, bleeding, allergic reaction, arrhythmia, acute kidney injury, tumor lysis, or any life-threatening change.
System failure	Unable to reach the CAR-T team; transport/admission delay; no bed; medication unavailable; caregiver failure; monitoring or EHR outage.

Universal first actions

- Identify the patient as a recent CAR-T recipient; confirm product and infusion date.
- Determine exact location, callback number, caregiver presence, and immediate transport options.
- Assess airway, breathing, circulation, vital signs, mental status, and immediate danger.
- Activate 911/EMS for life-threatening symptoms; do not delay for routine triage completion.
- Notify the designated CAR-T clinician and initiate the approved syndrome pathway.
- Consider CRS and infection concurrently; one diagnosis does not exclude the other.
- Document symptom onset, grading elements, calls, orders, treatments, transport, handoffs, and response times.

Roles and Decision Rights

Role	Minimum responsibility	Primary / backup / phone
Patient/caregiver	Recognize changes; perform assigned checks; call immediately; follow destination/transport instructions; do not self-treat fever unless instructed.	
Triage nurse / answering service	Identify CAR-T status; use scripted red-flag screen; connect to trained clinician; maintain closed-loop communication.	
CAR-T APP/physician	Direct assessment, grading, treatment, disposition, admission/ICU consultation, and handoff; resolve conflicting pathways.	
Clinic nurse	Immediate vital signs and neurologic screen; obtain access/specimens; administer approved treatment; monitor response; prepare transfer.	
Pharmacist	Verify and expedite medications; support dosing/compatibility; confirm stock; document preparation and administration times.	
ED team	Rapid identification and stabilization; contact CAR-T service; perform approved workup/treatment; expedite disposition.	
Admitting service / bed management	Accept and prioritize transfer; identify destination; communicate bed readiness and barriers.	
ICU / rapid response	Support unstable or high-grade toxicity; advise/accept transfer; coordinate critical care interventions.	
Transport / EMS	Use defined destination and urgency; receive CAR-T handoff; communicate delays or deterioration.	
Cell therapy coordinator	Maintain contacts, education, lodging/transport data, and communication across transitions.	
Program/quality leader	Review deviations and response times; authorize pause/CAPA; maintain playbook and simulations.	

First-Call Triage Script

IMMEDIATE EMERGENCY SCREEN

If seizure, loss of consciousness, inability to awaken, severe respiratory distress, cyanosis, collapse, or another immediately life-threatening condition is present: instruct the caller to activate 911 now; remain connected when feasible; notify the CAR-T clinician and receiving site.

Step	Required question / action	Finding
Identity	Patient name/MRN; CAR-T product; infusion date/day; treating center.	
Location	Exact address/location; callback number; caregiver present; travel time.	
Chief concern	What changed? Exact onset and trajectory?	
Vital signs	Temperature, blood pressure, pulse, oxygen saturation, respiratory rate if available.	
Neurologic status	Awake? Oriented? Speech/writing change? Tremor/weakness? ICE result if trained.	
Other symptoms	Chills, dyspnea, dizziness, chest pain, rash, bleeding, vomiting/diarrhea, low intake/urine.	
Recent care	Last clinic visit/labs; recent CRS/ICANS grade; prior tocilizumab/steroid/antimicrobial use.	
Medications	What was taken since symptoms began? Do not recommend antipyretics outside approved protocol.	
Logistics	Can patient travel safely? Who will drive? Is EMS required?	
Closed loop	Repeat destination, transport, contact, and what to do if condition worsens.	

Triage disposition

Disposition	Select	Clinician / time	Destination / ETA	Instructions
911 / EMS				
Immediate clinic evaluation				
Direct admission				
Emergency department				
Other approved pathway				

Possible CRS Response Pathway

Published outpatient models emphasize rapid evaluation and early intervention; one cohort used daily day-hospital assessment and outpatient tocilizumab for grade 1 or higher CRS under its protocol.⁷ Treatment must follow the center's current, product-aware algorithm and approved toxicity-grading framework.⁸

Stage	Required operational actions	Owner / target	Complete / time
Recognize	Treat fever and compatible hypotension/hypoxia as possible CRS while evaluating infection and other causes.	Triage/clinician Target: _____	
Assess	Full vital signs; focused exam; CRS grade using approved criteria; concurrent neurologic assessment; obtain ordered labs/cultures/diagnostics. ⁸	Clinic/ED clinician Target: _____	
Stabilize	Airway/oxygen, IV access, fluids and other supportive care per protocol; activate higher-acuity support when unstable.	Clinical team Target: _____	
Treat	Initiate institution-approved antipyretic, antimicrobial, tocilizumab, corticosteroid, and supportive-care orders as clinically indicated.	Prescriber/pharmacy/nursing Target: _____	
Reassess	Repeat vitals and grade at defined intervals; document response, cumulative therapy, and new neurologic findings.	Clinical team Frequency: _____	
Disposition	Apply explicit outpatient observation, admission, and ICU criteria. Activate transport and handoff without waiting for deterioration.	CAR-T clinician Target: _____	

CRS decision record

Element	Documentation
Symptom onset / first call	
First clinical assessment / initial grade	
Potential infectious source / workup	
First intervention and time	
Tocilizumab ordered / available / started	
Corticosteroid decision / administration	
Reassessment findings / grade	
Admission or ICU trigger met	
Disposition / accepting clinician	

DO NOT ANCHOR

Fever after CAR-T therapy may reflect CRS, infection, or both. Follow the approved neutropenic fever/sepsis process alongside CRS assessment when indicated.

Possible ICANS / Neurologic Toxicity Pathway

Stage	Required operational actions	Owner / target	Complete / time
Recognize	Treat new attention, language, writing, orientation, motor, alertness, or seizure findings as urgent.	Any team member Target: immediate	
Assess	ICE assessment when applicable; consciousness, motor findings, seizure activity, and other grading elements; compare with baseline.	Trained clinician Target: _____	
Protect	Fall and aspiration precautions; seizure precautions; avoid unapproved sedating medications; stabilize airway when needed.	Clinical team Target: _____	
Escalate	Notify CAR-T clinician; activate neurology, rapid response, ICU, imaging, EEG, or other support per algorithm.	CAR-T clinician Target: _____	
Treat	Administer corticosteroid, antiseizure medication, and other therapy only per approved ICANS/neurologic pathway. Treat concurrent CRS separately as indicated.	Prescriber/pharmacy/nursing Target: _____	
Disposition	Use explicit admission/ICU criteria; arrange monitored transport appropriate to current neurologic status.	CAR-T clinician Target: _____	

Neurologic assessment record

Element	Baseline	Current	Change / action
ICE score / components			
Level of consciousness			
Speech / naming / commands			
Writing			
Tremor / motor weakness			
Seizure activity			
Headache / focal signs			
Concurrent CRS findings			

EMERGENCY NEUROLOGIC SIGNS

Seizure, loss of consciousness, inability to awaken, rapidly worsening mental status, focal deficit, or airway compromise requires immediate emergency response and higher-level care.

Fever, Infection, and Other Acute Events

Concurrent fever / infection pathway

Action	Local specification	Completed / time
Neutropenic fever or sepsis pathway activation criteria		
Cultures and laboratory studies		
Imaging / source evaluation		
Empiric antimicrobial selection and administration target		
Fluid / oxygen / vasopressor escalation		
CRS assessment and treatment in parallel		
Admission / ICU criteria		
Isolation / infection-prevention needs		

Other event routing

Event	Immediate considerations	Local algorithm / destination
Hypotension / syncope	CRS, sepsis, dehydration, bleeding, cardiac causes; stabilize and escalate based on perfusion and response.	
Hypoxia / dyspnea	CRS, infection, fluid overload, pulmonary embolism, cardiac cause; oxygen and urgent assessment.	
Bleeding / severe cytopenia	CBC/coagulation, transfusion pathway, source control, admission based on severity.	
Chest pain / arrhythmia	Emergency cardiac assessment; do not assume CAR-T toxicity alone.	
Severe GI symptoms / poor intake	Volume/electrolytes, infection, medication effects; treat and determine safe setting.	
Other serious / product-specific or delayed toxicity	Consider IEC-HS/HLH-MAS-like hyperinflammation, delayed/non-ICANS neurologic toxicity, or IEC-associated enterocolitis when applicable. Activate the product- and institution-specific pathway; evaluate infection and alternative diagnoses in parallel; involve cellular therapy and specialty/ICU support early.	
Tumor lysis / renal dysfunction	Laboratory assessment, fluids and disease-specific management; admission as indicated.	
Allergic / infusion reaction	Stop/adjust infusion per approved protocol; emergency medications and escalation.	
Caregiver or monitoring failure	Activate backup; bring patient for assessment; convert to inpatient monitoring if safety cannot be restored.	

In-Hours Clinic Escalation

Step	Clinic action	Primary owner	Time / status
1. Activate	Announce CAR-T urgent evaluation; notify clinician, charge nurse, and pharmacist; assign recorder.		
2. Place	Move to designated assessment/stabilization space; obtain emergency equipment; start precautions.		
3. Assess	Vital signs, focused exam, CRS/ICANS assessment, access, labs/cultures/diagnostics.		
4. Treat	Use approved order set; expedite medications; document order-to-start time.		
5. Decide	Continue observed outpatient treatment only if explicit criteria are met; otherwise activate admission/transfer.		
6. Transfer	Closed-loop acceptance, bed/destination, transport, prearrival handoff, records, medication history.		
7. Close	Notify caregiver; reconcile orders; event record; immediate debrief for delays or deviations.		

Clinic readiness board

Capability	Location / contact	Ready?
CAR-T assessment room / chair		
Crash cart / oxygen / monitoring		
Tocilizumab access / stock / retrieval per current labeling and pathway		
Corticosteroids / seizure medications		
Antimicrobials / IV fluids		
Laboratory / cultures / imaging		
Rapid response / ICU consult		
Direct admission / bed management		
Transport / EMS		

After-Hours Escalation

Expert recommendations call for 24/7 access to specialized cancer care, predefined admission criteria, and direct-admission or ED partnerships.²

Step	Required after-hours action	Named role / number	Fallback
Call received	Identify CAR-T patient; complete emergency screen; record location/callback.		
Clinical connection	Connect directly to trained CAR-T clinician within local target.		
Destination decision	Select 911/EMS, ED, 24-hour oncology clinic, or direct admission.		
Prearrival notification	Notify receiving clinician/unit, pharmacy, and bed/ED leadership.		
Transport	Confirm driver/EMS, ETA, destination, and deterioration instructions.		
Handoff	Send product/date, symptoms, vitals, grade, medications, allergies, labs, and requested actions.		
Track arrival	Assigned team member confirms patient arrival and acceptance; escalates delay.		

Failed-contact pathway

- If the patient/caregiver cannot reach the primary line, use: _____
- If the CAR-T clinician does not respond within _____ minutes, call: _____
- If the receiving site does not accept or no bed is available, escalate to: _____
- If transport is delayed beyond _____ minutes or condition worsens, activate: _____
- The person responsible for confirming arrival is: _____

CLOSED-LOOP REQUIREMENT

The workflow is not complete when advice is given. Confirm that the patient reached the designated site and that clinical responsibility was accepted.

Direct Admission, ED, and ICU Handoff

Direct-admission pathway

Operational element	Local process / contact	Backup if unavailable
Accepting service / clinician		
Bed management / priority designation		
Designated landing bed or unit		
Prearrival orders / encounter creation		
Transport method		
Nurse-to-nurse / clinician handoff		
Pharmacy notification		
No-bed escalation		
ICU consultation / acceptance		

CAR-T transfer handoff

Handoff element	Information
Patient name / MRN / location / callback	
Diagnosis / CAR-T product / infusion date and day	
Chief concern / onset / trajectory	
Vital signs / oxygen / hemodynamic support	
CRS grade and supporting findings	
ICE score / ICANS grade and findings	
Infection workup / neutropenia / antimicrobials	
Tocilizumab / corticosteroid / seizure treatment with times	
Access, allergies, code status, isolation	
Pending labs / imaging / consultations	
Requested destination and urgency	
Sending and accepting clinicians / time	

Medication and Order Readiness

Programs should ensure rapid access to tocilizumab and other toxicity-management medications according to current product labeling and institution-approved pathways. ASTCT experts proposed tracking the interval from tocilizumab order to infusion start, with less than 1 hour as an operational benchmark.^{2,5}

Medication / resource	Indication pathway	Location / quantity	After-hours access	Prep / delivery target	Backup
Tocilizumab (per current labeling/pathway)					
Corticosteroid(s)					
Antiseizure medication					
Antimicrobials					
IV fluids					
Vasopressor access					
Oxygen / respiratory support					
Blood products					
Other: _____					

Order-set and pharmacy verification

- Approved CRS, ICANS, neutropenic fever/sepsis, and supportive-care order sets are accessible in all treatment locations.
- Weight, allergies, interactions, organ function, and cumulative doses can be verified rapidly.
- Pharmacy receives automatic or direct urgent notification.
- Medication can be dispensed to clinic, ED, inpatient unit, and after-hours site without avoidable administrative delay.
- Stock outages, refrigerator failure, preparation delay, and competing emergencies have defined backups.
- Order, verification, preparation, delivery, and administration timestamps are captured.

LOCAL CLINICAL CONTENT REQUIRED

Insert current institution-approved doses, repeat-dose rules, maximums, sequencing, antimicrobial choices, seizure prophylaxis/treatment, and product-specific instructions into the linked order sets—not as uncontrolled free text in this playbook.

One-Page Rapid-Escalation Map

1. RECOGNIZE	2. ACTIVATE	3. ASSESS + STABILIZE	4. TREAT	5. DISPOSITION	6. CLOSE LOOP
Fever / chills Hypotension / hypoxia Confusion / writing change Seizure / reduced alertness Any rapid deterioration	Confirm CAR-T product/date Life threat? Call 911/rapid response Notify CAR-T clinician Start event clock	Airway/breathing/circulation Full vital signs CRS + ICANS assessment Infection evaluation in parallel IV access / labs as ordered	Use approved CRS/ICANS/sepsis and product-specific toxicity orders Expedite indicated tocilizumab, steroid, antimicrobial, and supportive care Reassess and document	Apply explicit observation/admission/ICU criteria Accepting clinician + destination Transport matched to acuity	Handoff completed Arrival/acceptance confirmed Medication and response times captured Debrief delays/deviations

Emergency contacts

CAR-T clinician 24/7	Clinic / 24-hour unit	ED / direct admission	ICU / rapid response	Pharmacy	Transport / EMS

NEVER DELAY EMERGENCY RESPONSE

For seizure, loss of consciousness, severe breathing difficulty, collapse, or another immediately life-threatening condition, activate emergency response first.

Simulation and Validation

Scenario	Capabilities tested	Pass / revise	Corrective action / owner / due
After-hours fever at lodging	Call routing, CRS/infection screen, destination, transport, prearrival medication readiness.		
New writing and attention change	ICE/ICANS recognition, seizure precautions, steroid pathway, monitored transfer.		
Hypotension in clinic	Stabilization, rapid response, treatment, direct admission/ICU acceptance.		
No inpatient bed	Safe holding area, continuing treatment, leadership and backup-site escalation.		
Tocilizumab unavailable	Inventory check, alternative stock route, pharmacy escalation, safe disposition.		
Caregiver calls 911	EMS communication, ED alert, CAR-T handoff, team consultation.		
Delayed neurologic or severe/prolonged GI symptoms	Recognize product-specific delayed toxicity; activate cellular therapy and neurology/GI pathways as appropriate; evaluate infection and competing causes; determine safe disposition.		
EHR / phone downtime	Patient identification, paper orders, contact redundancy, timestamp capture.		

Acceptance criteria

- Life-threatening symptoms trigger immediate emergency response.
- Correct syndrome pathways are activated without diagnostic anchoring.
- Required medications, staff, equipment, and destinations are available.
- Every transfer has a named accepting clinician and closed-loop arrival confirmation.
- Response timestamps are captured accurately.
- Observed gaps are corrected, retested, and documented before launch.

Downtime and Contingency Playbook

Failure	Immediate safe state	Escalation / backup	Owner
24/7 phone failure	Use published backup number; answering service activates downtime tree.		
EHR unavailable	Paper CAR-T identification, assessment, grading, orders, and handoff; reconcile later.		
Medication unavailable	Notify clinician/pharmacy; retrieve from validated backup; reassess safe location.		
Laboratory delay	Use emergency/point-of-care pathway; do not delay stabilization or indicated transfer.		
No bed / admission delay	Use designated landing area or ED; continue treatment; escalate leadership.		
Transport delay	Match monitoring/staff to acuity; activate alternate/EMS; call 911 if worsening.		
Severe weather	Preemptive lodging/monitoring plan; alternate route/site; inpatient conversion if needed.		
Caregiver unavailable	Activate backup; immediate clinical review; inpatient monitoring if support cannot be restored.		
Clinic staffing failure	Activate contingency roster; stop new outpatient infusions if minimum coverage unmet.		

PAUSE AUTHORITY

Name the role authorized to pause outpatient infusion or monitoring when a critical capability is unavailable:

Event Record and Immediate Debrief

Event information	Documentation
Patient / product / infusion date	
Date / location / reporter	
First symptom and onset	
First call / triage / clinician contact times	
Initial vital signs / CRS / ICANS findings	
Other serious / product-specific toxicity findings	
Orders and treatment administration times	
Transport request / departure / arrival	
Accepting clinician / bed / unit	
ED / admission / ICU disposition	
Patient outcome / current status	

Debrief prompts

Question	Finding / action
Was toxicity recognized at the earliest reasonable point?	
Did the correct in-hours/after-hours pathway activate?	
Were CRS, ICANS, infection, other serious/product-specific toxicities, and competing causes assessed appropriately?	
Were medications and supportive care available without avoidable delay?	
Did transfer and acceptance occur as designed?	
Were the patient and caregiver instructions effective?	
What deviation, near miss, or system barrier occurred?	
Is immediate correction, formal CAPA, retraining, or program pause required?	

Quality Dashboard and Review

Recommended outpatient measures include admission/readmission, ED use, ICU transfer, time from bed request to readiness, time from tocilizumab order to administration, and Grade 3/4 CRS onset/recognition to ICU transfer.²

Domain	Measure	Definition / source	Target / limit	Result / action
Recognition	Symptom onset/first caregiver recognition to first call			
Access	First call to trained clinician response			
Evaluation	First call to in-person assessment			
Medication	Order to tocilizumab infusion start; antimicrobial order to administration			
Admission	Bed request to bed ready; request to physical arrival			
Transfer	Grade 3/4 CRS onset/recognition to ICU transfer			
Utilization	ED visits, admissions/readmissions, ICU transfers			
Clinical	CRS/ICANS incidence, grade, onset, recurrence, treatment			
Reliability	Protocol deviations, failed contacts, medication/transport/bed delays			
Experience	Patient/caregiver understanding, confidence, burden, and access barriers			

Review cadence

Review	Timing	Required participants	Decision / output
Immediate event debrief	Same shift or next business day	Clinical/operational participants	Immediate containment and owner
Pilot case review	Every initial outpatient case	Multidisciplinary CAR-T team	Continue, modify, or pause
Quality review	Monthly/quarterly per phase	Program, quality, ED/ICU, pharmacy	Trends, CAPA, policy/training change
Annual validation	At least annually and after major change	All pathway owners	Simulation, contact/order verification, approval

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