

Outpatient CAR-T Program Readiness Assessment and Implementation Roadmap

A structured tool to evaluate capability, close operational gaps, validate safety, and authorize a phased outpatient launch

PURPOSE

Designed for cellular therapy programs and community-based centers evaluating outpatient CAR T-cell infusion and early postinfusion monitoring. The tool supports local decision-making; it does not replace current product labeling, applicable FDA and other regulatory requirements, accreditation/quality standards, payer rules, or institutional policies.

Intended users

- Cellular therapy and hematologic malignancy program leaders
- Physicians, advanced practice providers, nurses, pharmacists, and cell therapy coordinators
- Emergency, critical care, laboratory, transfusion, quality, finance, and administrative partners

Development basis

The assessment domains and roadmap synthesize an ASTCT expert-panel opinion, implementation reviews, a contemporary outpatient cohort, and community program examples.

How to Use This Toolkit

Outpatient CAR-T delivery requires coordinated capabilities across patient selection, caregiver support, clinic access, toxicity response, rapid admission, workforce preparation, financial planning, and continuous quality improvement.¹⁻⁴

Recommended assessment process

1. Appoint an executive sponsor and a multidisciplinary assessment lead.
2. Complete the assessment as a team; do not allow one discipline to score the program alone.
3. Score current, demonstrable capability—not intent, work in progress, or informal knowledge.
4. Attach objective evidence and assign one accountable owner for every gap.
5. Resolve all Critical Launch Requirements before the first outpatient infusion.
6. Validate workflows through tabletop review and simulation before launch.
7. Begin with a defined pilot population and review every initial case before expansion.

Scoring scale

Score	Definition	Required evidence
0	Not in place	No approved process, assigned owner, or reliable capability.
1	Partially in place	Drafted, inconsistently available, unvalidated, or dependent on an individual workaround.
2	Fully in place	Approved, resourced, operational, tested, and supported by objective evidence.
N/A	Not applicable	A documented rationale is approved by program and quality leadership.

Readiness calculation

FORMULA

Domain readiness % = points earned ÷ (2 × number of applicable criteria) × 100. Overall readiness % uses the same formula across all applicable criteria. A high percentage does not override an unmet Critical Launch Requirement.

Interpretation	Range	Action
Not ready	<60%	Build foundational capabilities before scheduling a pilot.
Developing	60%-79%	Close priority gaps; repeat assessment before validation.
Validation ready	80%-89%	Proceed to simulation only if all critical items are at least partially implemented.
Launch ready	≥90%	Eligible for launch review only if every critical item scores 2 and simulations pass.

Local governance note: These thresholds are implementation aids, not externally validated standards. Each institution should approve its own decision rules and may adopt stricter requirements.

Domain 1. Governance, Regulatory, and Program Scope

Formal governance, defined scope, compliant policies, and a controlled pilot create the foundation for safe outpatient operations.¹⁻³

ID	Launch requirement	Criterion	Score 0/1/2/N/A	Evidence / gap	Owner / due date
1.1	CRITICAL	Accountable outpatient CAR-T medical/program director is formally designated.			
1.2	CRITICAL	Program scope defines eligible products, diseases, age groups, infusion location, monitoring model, and hours of operation.			
1.3	CRITICAL	Current product labeling, manufacturer requirements, applicable FDA/regulatory requirements, and adverse-event reporting processes are incorporated into policy. ⁵			
1.4	CRITICAL	Authorized treatment-center, applicable accreditation/quality standards, institutional, legal, compliance, and risk-management requirements have been reviewed and documented. ⁶			
1.5		A multidisciplinary governance committee has defined membership, decision rights, meeting cadence, and escalation authority.			
1.6	CRITICAL	Approved SOP set covers the full journey from referral and apheresis through infusion, monitoring, toxicity management, admission, and day-30 review.			
1.7		Document-control process identifies policy owners, approval dates, review cycles, and change management.			
1.8		Pilot charter defines starting volume, eligible constructs/population, stopping rules, expansion criteria, and review cadence.			

Domain score: ____ / ____ possible = ____% Assessor(s): _____ Date: _____

Domain 2. Multidisciplinary Team, Staffing, and Competency

Published recommendations consistently emphasize a specialized multidisciplinary team, 24/7 coverage, and competency across outpatient and emergency settings.¹⁻⁴

ID	Launch requirement	Criterion	Score 0/1/2/N/A	Evidence / gap	Owner / due date
2.1	CRITICAL	Named core team includes physician, APP, nurse, pharmacist, cell therapy coordinator, social worker/case manager, quality, data, and finance representation.			
2.2	CRITICAL	Outpatient staffing model supports planned infusion and daily high-risk follow-up, including weekends and holidays.			
2.3	CRITICAL	A qualified CAR-T clinician is reachable 24/7 with defined response expectations and backup coverage.			
2.4	CRITICAL	ED, ICU, hospitalist/admitting, bed management, rapid response, pharmacy, laboratory, and transfusion partners have assigned roles.			
2.5	CRITICAL	Role-specific initial competency covers CRS; ICANS/ICE assessment; infection/sepsis; cytopenias; IEC-HS/HLH-MAS; other serious, product-specific, or delayed toxicities when applicable; escalation and transfer; and emergency medications.			
2.6		Competency validation uses knowledge assessment, observed practice, and simulation—not attendance alone.			
2.7		Annual and event-triggered re-education is scheduled; competency completion is tracked.			
2.8		Staffing contingency plan addresses call-outs, surge volume, after-hours events, and simultaneous unstable patients.			

Domain score: ____ / ____ possible = ____% Assessor(s): _____ Date: _____

Domain 3. Clinical Infrastructure, Pharmacy, and Operations

Essential capabilities include daily evaluation, timely diagnostics and medications, safe cell handling, and outpatient capacity to stabilize or treat early toxicity.^{1-3,7}

ID	Launch requirement	Criterion	Score 0/1/2/N/A	Evidence / gap	Owner / due date
3.1	CRITICAL	Dedicated or designated outpatient space can safely infuse and observe CAR-T recipients with appropriate emergency equipment. If applicable, onsite cell collection space is defined and meets quality standards set by the manufacturer.			
3.2	CRITICAL	Clinic access and daily assessment capability are available throughout the product- and institution-defined high-risk period, including weekends/holidays.			
3.3	CRITICAL	Timely laboratory, blood bank/transfusion, radiology, pharmacy, and microbiology support are available.			
3.4	CRITICAL	Cell receipt, storage, preparation, transport, chain of identity/custody, and excursion response are validated for the outpatient site.			
3.5	CRITICAL	Tocilizumab and corticosteroids are available in the quantity and timeframe required by current product labeling and the institution-approved toxicity pathway and can be dispensed/administered without avoidable delay.			
3.6	CRITICAL	Supportive medications, anti-infectives, blood products, IV fluids, and resuscitation supplies are defined and stocked.			
3.7	CRITICAL	Scheduling and coordination address bridging-therapy washout when applicable, confirmation of product availability, lymphodepletion, early-day CAR-T infusion, required observation, same-day intervention, and escalation.			
3.8		EHR includes standardized treatment plans, order sets, flowsheets, handoffs, alerts, and documentation templates.			
3.9		Downtime procedures support safe care when EHR, phones, monitoring, laboratory, or transportation systems fail.			

Domain score: ____ / ____ possible = ____% Assessor(s): _____ Date: _____

Domain 4. Toxicity Recognition, Escalation, and Transitions of Care

Outpatient feasibility depends on rapid recognition, prompt intervention, and an admission pathway that functions in real time.^{1,2,4,7}

ID	Launch requirement	Criterion	Score 0/1/2/N/A	Evidence / gap	Owner / due date
4.1	CRITICAL	Approved algorithms address CRS, ICANS, infection/sepsis, hypotension, hypoxia, cytopenias, and other acute complications.			
4.2	CRITICAL	Admission and ICU-transfer criteria are explicit, product-aware, and linked to an operational pathway.			
4.3	CRITICAL	A 24/7 triage route connects patients/caregivers directly to clinicians trained in CAR-T assessment.			
4.4	CRITICAL	Direct-admission pathway identifies accepting service, bed request, transport, handoff, orders, and backup route if no bed is available.			
4.5	CRITICAL	ED pathway includes prearrival notification, patient identification/alert, immediate assessment expectations, and CAR-T team consultation.			
4.6	CRITICAL	Transport plan defines who activates transport, acceptable response time, destination, accompanying documentation, and escalation during delay.			
4.7		In-hours and after-hours workflows have been mapped separately and tested.			
4.8	CRITICAL	Tabletop and live simulations demonstrate timely recognition, treatment, handoff, and admission for representative CRS and ICANS scenarios.			
4.9		Post-event debrief and incident-review process produces documented corrective and preventive actions.			

Domain score: ____ / ____ possible = ____ % Assessor(s): _____ Date: _____

Domain 5. Patient Selection, Caregiver Support, and Monitoring

Selection should integrate clinical risk with caregiver capability, proximity, transportation, communication, and a reliable monitoring plan.¹⁻⁴

ID	Launch requirement	Criterion	Score 0/1/2/N/A	Evidence / gap	Owner / due date
5.1	CRITICAL	Written outpatient eligibility criteria address clinical status, disease burden/risk, comorbidities, functional status, cognition, psychosocial factors, and product toxicity profile.			
5.2	CRITICAL	A multidisciplinary approval process documents eligibility and permits reassessment when conditions change.			
5.3	CRITICAL	Local lodging and travel-time requirements are defined for the relevant monitoring period, with a transportation backup plan.			
5.4	CRITICAL	A qualified caregiver is available during the product- and institution-defined high-risk period; backup caregiver requirements are specified.			
5.5	CRITICAL	Caregiver capability is assessed using defined criteria and teach-back/return demonstration.			
5.6	CRITICAL	Patient/caregiver education covers CRS, neurologic toxicities, other serious or product-specific acute and delayed adverse effects when applicable, monitoring, ICE or neurologic checks when used, medications, contact routes, and emergency actions.			
5.7	CRITICAL	Home-monitoring method, frequency, documentation, review responsibility, abnormal thresholds, and response expectations are defined and tested.			
5.8		Equity plan addresses language, health literacy, disability, digital access, lodging, transportation, food, employment, and caregiver burden.			

Domain score: ____ / ____ possible = ____% Assessor(s): _____ Date: _____

Domain 6. Finance, Data, Quality, and Sustainability

Financial viability and safety should be monitored together through payer workflows, operational metrics, structured case review, and continuous improvement.¹⁻⁴

ID	Launch requirement	Criterion	Score 0/1/2/N/A	Evidence / gap	Owner / due date
6.1	CRITICAL	Payer-specific authorization, site-of-care, single-case agreement, admission-conversion, coding, and claims workflows are defined before scheduling.			
6.2	CRITICAL	Drug acquisition and reimbursement exposure is reviewed for outpatient and potential subsequent inpatient care.			
6.3		Financial counseling and patient-assistance pathways address lodging, transport, food, caregiver, and out-of-pocket costs.			
6.4	CRITICAL	Baseline and postlaunch dashboard includes admissions/readmissions, ED use, ICU transfers, CRS/ICANS, treatment times, length of stay, and safety events.			
6.5	CRITICAL	Operational measures include time from call to assessment; bed request to bed availability/readiness and to patient admission; tocilizumab order to administration; and high-grade CRS onset to ICU transfer.			
6.6		Financial measures include authorization cycle time, denials, net reimbursement, avoidable cost, and inpatient days avoided.			
6.7		Patient/caregiver experience and burden are measured using a defined method.			
6.8	CRITICAL	Every pilot case receives a structured review; aggregate performance is reviewed at a defined quality meeting.			
6.9	CRITICAL	Predefined pause/stop criteria and corrective-action authority are documented.			
6.10		Annual sustainability review addresses volume, staffing, access, outcomes, equity, reimbursement, and expansion readiness.			

Domain score: ____ / ____ possible = ____% Assessor(s): _____ Date: _____

Readiness Summary and Gap Register

Domain	Points earned	Possible points	Readiness %	Critical items at 2?
1. Governance and scope				Yes / No
2. Team and competency				Yes / No
3. Infrastructure and operations				Yes / No
4. Toxicity and transitions				Yes / No
5. Patient/caregiver and monitoring				Yes / No
6. Finance, quality, and sustainability				Yes / No
OVERALL				Yes / No

Prioritized gap register

Priority	Criterion ID / gap	Risk if unresolved	Required action / evidence	Owner	Due date	Status
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

PRIORITIZATION RULE

Address unmet Critical Launch Requirements first, followed by gaps with the greatest patient-safety, regulatory, access, operational, or financial impact. A workaround should be time-limited, approved, and tested.

Implementation Roadmap

A phased launch allows teams to test workflows with a narrowly defined population, review early cases, and expand only after performance is acceptable.¹⁻⁴ Some experts recommend piloting selected constructs and conducting full quality reviews before broader expansion.

Phase	Suggested timing*	Core work	Exit evidence
Phase 0: Mobilize	Weeks 0-4	Confirm rationale and executive sponsorship; appoint leaders; define scope and pilot principles; complete baseline assessment.	Approved charter; governance map; baseline score; initial risk register.
Phase 1: Design	Months 1-3	Build policies, patient/caregiver criteria, staffing, pharmacy logistics, EHR tools, financial pathways, and measurement plan.	Approved workflow set; training plan; payer pathway; dashboard specification.
Phase 2: Build and validate	Months 3-6	Configure systems; stock medications; train staff; conduct tabletop reviews and live simulations across in-hours and after-hours pathways.	Competency records; simulation reports; corrective actions closed; launch dossier.
Phase 3: Controlled pilot	Months 6-9	Treat a small, predefined cohort; use enhanced operational oversight; review each case promptly; apply pause criteria when needed.	Case reviews; metric dashboard; deviations/CAPA; pilot recommendation.
Phase 4: Stabilize and scale	Month 9 onward	Confirm sustained safety and financial performance; refine selection; expand products, populations, volume, or sites sequentially.	Quarterly quality review; annual sustainability review; approved expansion decision.

*Illustrative timing only. Pace should reflect institutional complexity, accreditation and regulatory needs, staffing, technology, contracts, and the closure of safety-critical gaps.

Phase workplan

Milestone / deliverable	Accountable owner	Contributors	Target date	Status	Approval / evidence
				Not started / In progress / Complete	
				Not started / In progress / Complete	
				Not started / In progress / Complete	
				Not started / In progress / Complete	
				Not started / In progress / Complete	
				Not started / In progress / Complete	
				Not started / In progress / Complete	
				Not started / In progress / Complete	
				Not started / In progress / Complete	

Validation and Simulation Plan

Simulation should test the full care system, including after-hours triage, medication access, transportation, ED or direct admission, ICU escalation, and documentation.^{1,2,3}

Scenario	Capabilities to demonstrate	Pass / revise	Corrective action owner / date
Fever / grade 1 CRS during clinic hours	Recognition, assessment, cultures/antimicrobials as indicated, tocilizumab pathway, observation vs admission		
Fever after hours at lodging	Caregiver call, triage, transport, destination, prearrival communication, medication readiness		
New handwriting or ICE change	ICANS recognition, neurologic assessment, steroid pathway, seizure precautions, level-of-care decision		
Hypotension or hypoxia	Immediate stabilization, rapid response, admission/ICU transfer, handoff		
No inpatient bed available	Backup destination, leadership escalation, safe holding location, ongoing treatment		
EHR or phone downtime	Patient identification, paper orders, contact redundancy, documentation reconciliation		
Caregiver unavailable	Backup caregiver activation, lodging/transport resolution, conversion to inpatient monitoring if needed		

Minimum simulation acceptance criteria

- Correct clinical algorithm selected and initiated without unsafe delay.
- CAR-T team, accepting service, pharmacy, and transport contacts function as designed.
- Required medication and equipment are physically available and usable.
- Handoff contains product, infusion date, current toxicity grade, interventions, and pending needs.
- Observed gaps have owners, deadlines, retesting requirements, and documented closure.

Pilot Launch Authorization

LAUNCH STANDARD

Authorize the pilot only when every Critical Launch Requirement scores 2, overall readiness is at least 90%, required simulations pass, and accountable clinical, operational, quality, pharmacy, and financial leaders approve.

#	Authorization criterion	Verified by / date	Evidence location
1	Pilot population, products, volume, and exclusions are approved.		
2	All critical policies and workflows are current and accessible.		
3	Staffing and 24/7 coverage are confirmed for the pilot dates.		
4	Patient/caregiver eligibility, education, monitoring, lodging, and transport processes are ready.		
5	Tocilizumab, corticosteroids, supportive medications, blood products, and emergency equipment are ready.		
6	ED, direct-admission, ICU, and no-bed backup pathways have passed simulation.		
7	Cell handling and chain-of-identity/custody processes are validated for the site.		
8	Payer authorization and financial review are complete for the first patient.		
9	Dashboard, case-review process, event reporting, and pause criteria are active.		
10	Leadership has reviewed residual risks and formally accepted or mitigated each one.		

Approval

Role	Name	Decision	Signature / date
Medical/program director		Approve / Defer	
Nursing/outpatient operations		Approve / Defer	
Pharmacy		Approve / Defer	
Quality/safety		Approve / Defer	
Finance/revenue cycle		Approve / Defer	
Executive sponsor		Approve / Defer	

PILOT PAUSE TRIGGERS

Define institution-specific triggers before launch. Examples may include unexpected severe toxicity, delayed emergency medication, failed transfer/admission, critical staffing loss, product-handling deviation, serious communication failure, or a pattern suggesting selection criteria are inadequate.

Early Program Review

Case review template

Review element	Finding
Patient / product / indication	
Infusion date and monitoring model	
Eligibility deviations or exceptions	
CRS / ICANS onset, grade, and interventions	
ED visit, admission, ICU transfer, and length of stay	
Key response times	Call to assessment: ____ Bed request to bed available/readiness: ____ Bed request to admission: ____ Tocilizumab order to administration: ____ Grade 3-4 CRS onset to ICU transfer: ____
Caregiver / lodging / transport issues	
Medication, EHR, handoff, or staffing issues	
Patient/caregiver feedback	
Financial / authorization / claims issue	
Learning and required corrective action	
Continue / modify / pause	Reason: _____

Suggested initial dashboard

Measure	Definition / data source	Target / limit	Frequency	Owner
Outpatient infusions and percentage admitted				
Call-to-assessment time				
Bed request-to-bed availability/readiness and admission time				
High-grade CRS onset-to-ICU transfer				
CRS and ICANS incidence, grade, and onset; ED/ICU utilization and length of stay				
Tocilizumab use and order-to-administration time				
Protocol deviations, safety events, and corrective actions				
Outpatient days achieved/inpatient days avoided; authorization cycle time, denials, reimbursement; patient/caregiver experience and burden				

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