Community Practice Coordination With a CAR-T Treatment Center

Referral, bridging therapy, acute-period communication, transition, and long-term shared care

NOTE
This is an illustrative SOP—not an approved clinical policy.

Document control

Field	Entry	Field	Entry
Community practice	[NAME]	CAR-T center	[NAME]
SOP number	[NUMBER]	Version	[VERSION]
Effective date	[DATE]	Review date	[DATE]
Policy owner	[ROLE/NAME]	Supersedes	[VERSION/N/A]
Applies to	[SITES/DEPARTMENTS]	Related agreement	[TITLE/DATE]

Approvals

Role	Name	Signature	Date
Community medical director			
Community nursing leader			
Community pharmacy leader			
CAR-T program medical director			
CAR-T program operational leader			
Quality/compliance representative			

Related controlled documents / agreements

Document / agreement	Local identifier / version
Partner-site shared-care agreement / memorandum of understanding	[DOCUMENT ID / VERSION]
CAR-T toxicity-management, emergency-escalation, direct-admission, transfer, and receiving-ED pathways	[DOCUMENT ID / VERSION]
Leukapheresis / collection and chain-of-identity/custody procedures, if applicable	[DOCUMENT ID / VERSION]
Deviation/CAPA, staff training, and competency procedures	[DOCUMENT ID / VERSION]

1. Purpose

To establish a closed-loop process between [COMMUNITY PRACTICE] and [CAR-T CENTER] for early referral, candidacy evaluation, leukapheresis preparation, bridging therapy, transfer for lymphodepletion/infusion, acute toxicity communication, return to community care, and long-term monitoring of patients being considered for or treated with CAR-T therapy.

2. Scope

This SOP applies to physicians, advanced practice providers, nurses, pharmacists, social workers, financial/access staff, schedulers, laboratory staff, emergency personnel, and quality personnel involved in shared care. It does not authorize the community practice to administer CAR-T cells or independently manage suspected CRS or ICANS unless a separate, approved protocol explicitly grants that responsibility.

3. Policy

- The patient will have one current, jointly understood plan with a named owner for every action.
- Urgent clinical communication will use a live, 24/7 route; portals, faxes, and routine inboxes will not be used as the sole urgent pathway.
- Anticancer therapy, corticosteroids, immune-modifying therapy, prophylaxis, or other material medication changes during the CAR-T pathway require review according to the jointly approved plan.
- Bridging therapy will have a documented goal, regimen, monitoring plan, response assessment, last allowable dose, washout/recovery criteria, and contingency plan.
- Transfer back to community care requires a formal handoff and affirmative acceptance by the receiving clinician.
- Local policy, current labeling, accreditation requirements, payer requirements, and the CAR-T center's product-specific procedures supersede this example.

4. Definitions

Term	Operational definition
CAR-T center	The authorized treatment program responsible for candidacy, cellular product coordination, lymphodepletion, infusion, acute monitoring, cellular-therapy oversight, and required long-term follow-up.
Community cancer center	The referring/local oncology practice providing pre-referral care, approved bridging/supportive care, and agreed post-CAR-T follow-up.
Bridging therapy	Anticancer therapy administered between leukapheresis/product planning and lymphodepletion or infusion to control disease.
Closed-loop communication	A message or request is sent, received, acknowledged, acted on, and the decision is confirmed to the sender.
Acute monitoring period	The product- and center-defined period after infusion when the CAR-T center retains primary toxicity-management responsibility.
Transition	Formal transfer of specified care responsibilities, supported by a complete record and receiving-clinician acceptance.
Designated collection facility	The CAR-T center or separately authorized/qualified collection site assigned to perform leukapheresis under applicable manufacturer, accreditation, chain-of-identity/custody, and institutional procedures.

5. Responsibilities

Role	Required responsibilities
Referring community oncologist/APP	Recognize referral triggers; submit clinical packet; maintain disease control; obtain CAR-T approval for bridging plan; report clinical changes; accept and execute post-CAR-T plan.
Community nurse/coordinator	Track milestones; verify records; teach contact routes; schedule labs/visits; close communication loops; maintain shared-care log.
Community pharmacist	Reconcile medications; assess interactions, prophylaxis and supportive care; verify approved bridging orders, last doses and holds; communicate changes.
CAR-T physician/APP—clinical pathway owner	Determine candidacy; direct collection, bridging constraints, lymphodepletion, infusion, acute toxicity management, response assessment, and transition criteria.
CAR-T coordinator—operational pathway owner	Acknowledge referral; provide milestones and instructions; coordinate records, appointments, lodging/caregiver requirements, transition and urgent contacts.
CAR-T pharmacist	Provide product-/regimen-specific medication restrictions, washout/recovery guidance, lymphodepletion/supportive-care medication review, prophylaxis, interaction assessment, toxicity-management medication readiness, and medication handoff. If pharmacy performs cellular-product handling, follow the separate controlled cellular-product procedure.
CAR-T program leadership with community partner	Define service standards and ownership; maintain primary/backup contacts; reconcile discrepancies; conduct joint event review; approve material pathway changes.
Collection facility / apheresis team, if applicable	Verify collection readiness and vascular access; perform leukapheresis under the approved collection SOP; manage collection-related adverse events; maintain chain of identity/custody; package and release collected material; document courier handoff and deviations.

Required contact directory

Function	Community contact (Name/Email)	CAR-T contact (Name/Email)	Hours / backup
Physician/APP			
Nurse coordinator			
Pharmacist			
Scheduling/access			
24/7 urgent clinical line			
Transfer center / receiving ED			
Apheresis / collection facility, if applicable			

DIRECTORY CONTROL

The policy owner verifies contact routes at least [QUARTERLY] and whenever staffing, phone trees, transfer processes, or partner sites change.

6. Procedure A—Referral and Evaluation

A1. Identify and discuss: The community clinician considers referral early when the patient approaches a relevant line of therapy, has high-risk relapse/refractory disease, or may lose eligibility with delay. Uncertain candidacy is discussed with the CAR-T center rather than presumed ineligible.

A2. Obtain permission: The community practice documents the patient's agreement to referral and record exchange and explains that CAR-T evaluation does not guarantee treatment.

A3. Submit referral: The designated coordinator sends the minimum referral packet through [APPROVED METHOD] and labels clinical urgency.

A4. Acknowledge and triage: The CAR-T center acknowledges receipt within [TIME], identifies missing elements, assigns a clinical owner, and provides the consult date or disposition.

A5. Issue interim instructions: The CAR-T center states what therapy may continue while evaluation is pending and identifies any collection-related restrictions.

A6. Close the loop: The community coordinator records the decision, next milestone, owner, deadline, and confirmation in [EHR/LOG].

Minimum referral packet

Required item	Community sent	CAR-T received / acceptable
Diagnosis, pathology and molecular/target studies	☐	☐
Stage, current disease sites and recent imaging; images available	☐	☐
Complete treatment timeline, responses, refractory status and toxicities	☐	☐
Recent CBC/differential, CMP, LDH and disease-specific tests	☐	☐
Performance status, comorbidities, neurologic baseline and infection history	☐	☐
Medication/allergy list, corticosteroids, prophylaxis and anticoagulation	☐	☐
Insurance/access status and patient preference	☐	☐
Caregiver, transportation, lodging, distance, language and psychosocial needs	☐	☐
Proposed interim therapy and clinical urgency	☐	☐

Documentation standard

Referral is complete only when the CAR-T center confirms receipt, assigns an owner, and returns the next action. Missing information and its owner are documented; the referral is not silently closed.

7. Procedure B—Pre-Apheresis and Bridging Therapy

B1. Protect collection: Before leukapheresis, the community practice does not initiate or repeat anticancer treatment that could affect collection unless the CAR-T center approves it in writing or through a documented clinician-to-clinician decision.

B2. Create the bridging plan: After confirming the collection/manufacturing timeline, both physicians define the goal: stabilization, debulking, symptom relief, organ protection, or a combination.

B3. Assess risk: The plan accounts for disease biology and tempo, prior response, blood counts, infection, organ function, performance status, expected recovery, target/T-cell effects, and potential lymphodepletion delay.

B4. Authorize administration: The CAR-T clinician approves the regimen/modality, dose, schedule, administration site, supportive care, monitoring, response assessment, last allowable dose, washout/recovery criteria, hold/stop rules, and Plan B.

B5. Administer and monitor: The community practice administers only the current approved plan, reviews results on the assigned schedule, and reports every dose, hold, reduction, toxicity, infection, ED visit, admission, transfusion, or clinical decline.

B6. Reassess response: At the defined checkpoint, both sites review response, fitness, manufacturing status, and timing. Progression or nonresponse triggers same-day clinician review rather than an automatic additional cycle.

B7. Complete final handoff: Before lymphodepletion, the community practice sends the final treatment, toxicity, infection, laboratory, transfusion, medication, and disease-status record. The CAR-T center confirms proceed/hold status.

Bridging can preserve disease control during manufacturing, but regimen selection is individualized. Retrospective data in LBCL associated response to bridging with better post-CAR-T outcomes; studies in myeloma underscore that sequencing and immune/target effects remain evolving considerations.

Required bridging authorization

Field	Approved entry
Goal / target disease sites	
Apheresis date and precollection restrictions	
Regimen or radiation plan / administration site	
Start date, planned doses and last allowable dose	
Laboratory/visit schedule and results reviewer	
Supportive care, prophylaxis and transfusion thresholds	
Response assessment, date and criteria	
Washout and hematologic/organ recovery criteria	
Hold, stop and urgent escalation criteria	
Plan B for progression or manufacturing delay	
Approving clinicians, date/time and plan version	

8. Procedure C—Apheresis

C1. Confirm collection site and responsibility: The CAR-T center identifies the designated collection facility, responsible ordering clinician, manufacturer/product requirements, and applicable controlled collection procedure. If collection occurs outside the CAR-T center, the site must be separately authorized/qualified and included in the approved shared-care agreement.
C2. Verify precollection readiness: The responsible collection team verifies required laboratory testing, infection status, treatment holds/washouts, medications, consent/documentation, collection appointment, and any manufacturer-specific prerequisites before collection.
C3. Assess vascular access: The collection team determines whether peripheral access is adequate and arranges central venous access only when clinically required under the approved vascular-access process.
C4. Perform leukapheresis: Leukapheresis is performed under the designated facility's approved apheresis SOP, including patient identification, monitoring, anticoagulation, and management of collection-related adverse events.
C5. Maintain chain of identity and custody: Patient and collection identifiers are verified at required checkpoints. Chain-of-identity/custody documentation is completed according to manufacturer and institutional requirements.
C6. Inspect, package, and release collected material: Collected leukapheresis material and required documentation are inspected, packaged, and released for shipment under the applicable manufacturer and collection procedures.
C7. Complete courier handoff: Courier identity, pickup time, shipment/tracking information, and any delay, excursion, or packaging deviation are documented and escalated through the approved pathway.
C8. Communicate completion: The collection team confirms collection completion, patient tolerance, collected-material disposition, and any deviation or follow-up need to the CAR-T clinical and operational pathway owners and the community clinician as applicable.

C9. Resolve collection deviations: Any identity/custody discrepancy, collection failure, inadequate material, shipment problem, or other deviation is managed under the designated quality/deviation procedure. The CAR-T center communicates the interim plan and any effect on treatment timing.

Collection responsibility record

Field	Local entry
Designated collection facility	
Responsible ordering clinician	
Collection SOP / document ID / version	
Vascular access plan	
Manufacturer/product instructions / version	
Chain-of-identity/custody process	
Courier/shipping process	

9. Procedure D—Transfer for Lymphodepletion and Infusion

D1. Reconcile: The community coordinator sends the final record by [DEADLINE]. The CAR-T coordinator confirms receipt and identifies discrepancies.

D2. Verify readiness: The CAR-T center reviews recovery/washout, infection status, disease status, organ function, performance status, medications, caregiver, lodging, transportation, payer/access, and treatment setting.

D3. Issue decision: The CAR-T clinician documents proceed, delay, admission, additional evaluation, or alternate plan and communicates it to the community clinician.

D4. Update ownership: At the start of lymphodepletion, the CAR-T center becomes the primary clinical decision-maker for product-related treatment and toxicity through the defined acute period. The community practice remains available for history and local coordination.

Final transfer checklist

Community confirms	Done	CAR-T center confirms	Done
All bridging doses/holds and last dose	☐	Treatment record reconciled	☐
Disease status, symptoms, performance	☐	Candidacy/readiness reviewed	☐
Latest requested labs/tests	☐	Recovery/washout met	☐
Infections, cultures, antimicrobials	☐	Proceed/hold infection decision	☐
Toxicities, ED visits, admissions, transfusions	☐	Toxicities acceptable/mitigated	☐
Medication/allergy list	☐	Medication/prophylaxis plan reconciled	☐
Caregiver/logistics/access changes	☐	Monitoring plan finalized	☐
Future community contact	☐	Transition route and expected timing	☐

10. Procedure E—Acute-Period Communication

E1. Route urgent symptoms: Any fever, new neurologic change, hypotension, hypoxia, severe infection concern, bleeding, or rapid deterioration reported to the community practice is immediately routed to the CAR-T center's 24/7 line and emergency pathway.

E2. Do not delay disposition: The community practice activates emergency services for life-threatening illness while notifying the CAR-T center concurrently. It does not delay transport to obtain routine testing or await portal response.

E3. Limit independent treatment: The community practice does not independently treat suspected CRS or ICANS unless a separately approved protocol assigns that function. Emergency stabilization is never withheld.

E4. Document closure: The caller records time, recipient, read-back, disposition, destination, responsible clinician, and next communication time.

E5. Remote monitoring, if used: Any remote-monitoring platform must be institution-approved, have defined review/escalation ownership and downtime procedures, and must not replace the live 24/7 urgent clinical-contact pathway.

11. Procedure F—Return to Community Care

F1. Determine readiness: The CAR-T clinician determines that the patient meets center-defined transition criteria and identifies responsibilities that remain with the CAR-T program.

F2. Send transition packet: The CAR-T center sends the required record and conducts a live handoff for patients with unresolved toxicity, complex infection, prolonged cytopenia, or other high-risk needs.

F3. Accept care: The community clinician confirms receipt, capability, first appointment, result reviewer, escalation route, and open-issue owners. Lack of acceptance is escalated before transfer.

F4. Reconcile with patient: Both sites ensure the patient/caregiver has one medication list, monitoring schedule, appointment list, restriction list, and 24/7 contact route.

Required transition packet

Required element	Sent	Accepted
CAR-T product/target, lymphodepletion and infusion date	☐	☐
Disease status and response-assessment schedule	☐	☐
CRS/ICANS and other toxicities: grade, dates, treatment, residual effects	☐	☐
Infections, cultures and antimicrobial history	☐	☐
Current medications, prophylaxis, holds and review/stop dates	☐	☐
CBC/CMP and immune-recovery trends; transfusion/growth-factor plan	☐	☐
Immunoglobulin and relevant immune-recovery monitoring, including B-cell recovery when applicable, and immunoglobulin-replacement plan	☐	☐
Blood-product and central-line requirements	☐	☐
Visit/lab schedule and result ownership	☐	☐
Driving, proximity, caregiver and other active restrictions	☐	☐
Vaccination/revaccination plan	☐	☐
Urgent symptoms, first-call number, ED/transfer destination	☐	☐
Next CAR-T visit and long-term follow-up obligations	☐	☐
Serious/product-specific and delayed toxicities: residual risk, warning signs, responsible clinician, and escalation route	☐	☐
Secondary malignancy surveillance and reporting responsibilities	☐	☐

Transition acceptance record

Field	Entry
Accepting clinician / date and time	
First visit / first laboratory date	
Results reviewer / after-hours backup	
Medication reconciliation completed by	
Open issues / owner / due date	
Next CAR-T visit	
Urgent route tested and confirmed	

12. Procedure G—Post-CAR-T Monitoring

G1. Use the written schedule: The community practice performs only the tests, visits, prophylaxis, transfusion/growth-factor support, and other follow-up assigned in the current transition plan.

G2. Review results: The named clinician reviews results within [TIME]. Critical or threshold-crossing results are communicated live to the CAR-T center according to the plan.

G3. Screen at every visit: Assess disease symptoms, infection, bleeding, cytopenia symptoms, cognition/speech/tremor/weakness/gait, cardiopulmonary symptoms, organ function, nutrition, function, distress, caregiver strain, and medication adherence.

G4. Maintain immune-health plan: Follow the written antimicrobial, immunoglobulin/IVIG, and vaccination plan. Live vaccines are not administered unless specifically cleared under current guidance and the CAR-T center plan.

G5. Reconcile changes: New admissions, infections, transfusions, neurologic findings, disease progression, or significant medication changes are reported to the CAR-T center within the assigned urgency.

G6. Continue survivorship: Both sites maintain disease surveillance and long-term cellular-therapy follow-up/reporting responsibilities; annual plans are reconciled.

Post-CAR-T monitoring assignment

Domain	Community action	CAR-T oversight / escalation
Disease	Ordered imaging/marrow/disease tests; report new symptoms.	Set schedule; interpret; direct relapse workup.
Cytopenias	Trend CBC; bleeding/infection assessment; execute support plan.	Guide prolonged/recurrent cytopenia workup.
Infection	Urgent fever evaluation; prophylaxis/diagnostic plan.	Set prophylaxis and immune-recovery criteria.
Humoral immunity	Trend immunoglobulins and relevant immune-recovery parameters, including B-cell recovery when applicable; administer immunoglobulin replacement as ordered.	Set thresholds, replacement plan, and reassessment.
Neurologic/function	Screen cognition, speech, tremor, weakness, gait and function.	Evaluate persistent/new syndromes.
Organ health	Monitor renal, hepatic, cardiac/pulmonary and nutrition status.	Direct suspected treatment-related workup.
Vaccination	Execute written schedule; verify before live vaccine.	Define prerequisites and schedule.
Survivorship	Fatigue, cognition, distress, work/financial/caregiver needs.	Maintain cellular-therapy long-term oversight.
Delayed/product-specific toxicities	Screen per product-specific transition plan; report new concerning neurologic, GI, inflammatory, hematologic, or other findings.	Define product-specific warning signs, workup, and escalation route.
Secondary malignancies	Maintain lifelong surveillance; report suspected/new malignancy to CAR-T center promptly.	Coordinate manufacturer/FDA reporting and CAR-transgene testing instructions when applicable.

Local follow-up schedule

Timepoint	Tests / visit	Results owner	Escalation threshold
First visit after transition			
Weekly/risk-based early follow-up			
Day ~60			
Day ~90–100			
Month 6			
Month 12			
Annual/long-term			

13. Urgent Escalation Algorithm

Condition	Community response	CAR-T center response
Immediately life-threatening	Call emergency response/911; provide CAR-T card/product/date; notify CAR-T center concurrently.	Alert destination/transfer pathway; provide guidance; coordinate acceptance.
Urgent but stable	Live call to 24/7 route; provide onset, vitals, neurologic status, product/date and recent toxicities.	Return disposition and instructions; name receiving clinician/destination.
Threshold-crossing result	Same-day live communication; verify receipt and repeat plan.	Acknowledge; direct action; set review time.
Primary contact unavailable	Use backup/transfer center/ED route.	Maintain redundant, tested route.
Conflicting or unclear plan	Pause nonemergent change; escalate clinician-to-clinician.	Name final decision owner; issue time-stamped revised plan.

URGENT CALL SCRIPT

"This patient received CAR-T: [product], infused [date]. Current location: [site]. New problem and onset: [details]. Vitals and neurologic status: [data]. Recent CAR-T toxicities/treatments: [summary]. I need a disposition decision now. Call-back: [number]."

14. Required Records

- Referral packet and acknowledgment
- Shared contact directory
- Milestone and communication log
- Apheresis/precollection instructions
- Approved bridging plan and every revision
- Treatment administration, toxicity and response records
- Final pre-lymphodepletion handoff
- Acute urgent-call documentation
- Transition packet and receiving-site acceptance
- Post-CAR-T results, escalation notes and survivorship plan
- Training, competency and contact-route test records

15. Training and Competency

Before participating, staff complete role-specific education on the pathway, communication routes, bridging authorization, urgent symptoms, product/date identification, emergency handoff, documentation, and privacy. Competency is validated at onboarding and [ANNUALLY], and after a serious event or material process change.

Competency	Method	Frequency	Record location
Referral and closed-loop handoff	[TEACH-BACK / SIMULATION / AUDIT]	[FREQUENCY]	[LOCATION]
Bridging authorization and medication reconciliation	[TEACH-BACK / SIMULATION / AUDIT]	[FREQUENCY]	[LOCATION]
Urgent CAR-T call simulation	[TEACH-BACK / SIMULATION / AUDIT]	[FREQUENCY]	[LOCATION]
Transition acceptance and result routing	[TEACH-BACK / SIMULATION / AUDIT]	[FREQUENCY]	[LOCATION]

16. Quality Assurance and Review

Measure	Definition / review
Referral completeness	Required packet complete at first CAR-T review.
Timeliness	Referral-to-consult and consult-to-apheresis; avoidable delay reasons.
Bridging plan closure	Approved plan includes monitoring, response assessment, washout and Plan B before first dose.
Bridging outcome	Response/stability/progression, toxicity, delay, infection and proportion reaching infusion.
Handoff reliability	Milestone, final transfer and transition packets complete/on time.
Urgent response	Time from live escalation to disposition; transfer delay and preventability.
Follow-up reliability	Missed tests/visits, unreviewed results, medication discrepancies and loss to follow-up.
Equity/access	Timeliness/completion by distance, payer, language and demographic groups.

Events reviewed jointly within [TIMEFRAME]

- Failure to reach infusion potentially related to delay, progression, bridging toxicity, infection or access
- Unapproved therapy or medication change during the pathway
- Conflicting instructions or failed urgent contact route
- Unexpected ED visit, transfer delay, ICU admission or death
- Missed critical result, follow-up failure, or incomplete transition
- Patient/caregiver report that site responsibilities were unclear

17. Exceptions and Deviations

Emergent care may proceed when delay would threaten life or function. The responsible clinician documents the clinical rationale, actions, notifications, and follow-up. Nonemergent deviations require approval from [ROLE] and the CAR-T center clinical owner. Deviations are entered into [QUALITY SYSTEM] and reviewed for corrective action.

18. Review and Revision

The policy owner reviews this SOP at least [ANNUALLY] and sooner after product-label changes, new partner-site requirements, contact or transfer changes, serious events, audit findings, or changes in clinical evidence. Both organizations approve material revisions before implementation.

Revision history

Version	Effective date	Change summary	Author / approvals

Appendix A. Communication and Milestone Log

Date/time	Phase / issue	Sender → receiver	Decision / owner / deadline	Read-back / closed

Appendix B. Pre-Go-Live Verification

Verification	Community	CAR-T center	Evidence / owner
SOP approved and accessible	☐	☐	
Primary and backup contacts tested	☐	☐	
Urgent and transfer routes tested	☐	☐	
Referral packet fields configured	☐	☐	
Record exchange method validated	☐	☐	
Bridging authorization workflow validated	☐	☐	
Medication reconciliation responsibility assigned	☐	☐	
Final transfer checklist configured	☐	☐	
Transition acceptance workflow configured	☐	☐	
Critical result routing tested	☐	☐	
Staff competency completed	☐	☐	
First joint case review scheduled	☐	☐	

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