Bristol Myers Squibb®

Outpatient Monitoring

CAR T Cell Therapy in the Outpatient Setting

Outpatient infusion and monitoring may improve CAR T cell therapy access[1]

The decision to pursue inpatient vs outpatient administration of CAR T cell therapy lies with the provider[a] and is based on a number of different factors[2,b]

- CAR T cell therapy products have varying toxicity profiles and therefore HCPs, patients, and their caregivers need to be aware of the specific product's profile and AEs when infusing and monitoring[2,3]
- Not all patients who receive CAR T cell therapy are appropriate candidates for treatment in the outpatient setting[2,4]

[a]This assumes a setting-of-care-agnostic product label. [b]The decision of the CAR T cell therapy administration setting lies with the treating physician.[2]
AE, adverse event; HCP, healthcare provider.

References: 1. Bachier CR, et al. Abstract 8037. Presented at 2020 ASCO Virtual Scientific Program. **2.** Gatwood K, et al. *Clin Hematol Int.* 2024;6(2):11-20. **3.** Yanez L, et al. *HemaSphere*. 2019;3:2(e186). **4.** Smith S, Essell J. *J Clin Pathways*. 2018;4(8):42-47.

CAR T Academy: Outpatient Monitoring

01: PATIENT EXPERIENCE

02: IMPORTANCE OF A CAREGIVER

Journey Through the CAR T Cell Therapy Process

Icon indicates areas of collaboration between the non-CAR T and CAR T treatment teams

Patient identification[1,2]

- Appropriate patients are identified for treatment at qualified treatment sites or referring sites
- Early collaboration may facilitate timely referral and eligibility evaluation
- Once a patient is confirmed as eligible, leukapheresis is scheduled

Apheresis[1-4]

- Before apheresis, patients undergo a washout of prior medications that may affect T cell health to ensure optimal collection
- Physicians, APPs, and nurse coordinators all play a role in ensuring a proper washout occurs before apheresis
- Patients then undergo apheresis, which involves collection of white blood cells
- The collected apheresis product is then sent to the manufacturer

Manufacturing

Bridging[1,3]

- Bridging therapy may be given to maintain disease control during CAR T cell manufacturing
- Appropriate bridging therapy should be discussed and coordinated between the referring physicians and those treating with CAR T cell therapy

LDC and Infusion[1-3]

- LDC is administered prior to CAR T cell infusion to deplete endogenous T cells and create an environment for CAR T cell expansion
- Infusion will then occur at a qualified treatment center

Monitoring and long-term follow-up[1,2,5]

- After infusion, patients are closely monitored for at least 2 weeks at the CAR T cell therapy treatment site, and side effects are promptly managed
- After at least 2 weeks, patients may be discharged back to the referring physician's care
- Communication continues between the CAR T cell therapy treatment center and the primary hematologist/oncologist as patients are monitored long-term

APP, advanced practice provider; CAR, chimeric antigen receptor; LDC, lymphodepleting chemotherapy.

References: 1. Beaupierre A, et al. *J Adv Pract Oncol.* 2019;10(Suppl 3):29-40. **2.** Beaupierre A, et al. *Clin J Oncol Nurs.* 2019;23:27-34. **3.** McGuirk J, et al. *Cytotherapy.* 2017;19(9):1015-1024. **4.** Qayed M, et al. *Cytotherapy.* 2022;S1465-3249(22)00641-7. **5.** US Food and Drug Administration. Accessed June 27, 2025. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor

The CAR T Cell Infusion Setting

Factors to Consider When Determining CAR T Cell Infusion Settings[1]

- Treatment center infrastructure
- Ability to provide patient coverage 24/7
- CAR T cell product offered
- Availability of reliable caregiver(s)
- Anticipated onset and severity of AEs
- Training, education, and protocols for managing AEs

Some hospitals have moved to outpatient infusion for some CAR T cell therapy trials[2]

- Every CAR T cell therapy program requires the ability to:
  - Safely administer CAR T cell therapy[1]
  - Properly monitor and manage patients before, during, and following treatment[3]
- Treating physicians must determine the setting in which to safely deliver CAR T cell therapy[1]
- CAR T cell therapy is typically infused in the inpatient setting; however, ambulatory infusion is becoming increasingly common[1]

AE, adverse event.

References: 1. Taylor L, et al. *Clin J Onc Nurs.* 2019;23(2):20-26. **2.** Teachey DT, et al. *Nat Rev Clin Oncol.* 2018;15(4):218. **3.** Beaupierre A, et al. *Clin J Oncol Nurs.* 2019;23:27-34.

Considerations for Inpatient vs Outpatient Settings

Inpatient

- Staff that are educated about CAR T cell therapy should be present at all times while the patient is admitted; ICU staff should be trained on AE management[1]
- Compliance with standards for infection control required for cell therapy[1]
- Accessibility to ancillary services involved in the care of patients treated with CAR T cell therapy[2]
- Consideration toward inpatient bed management due to potential prolonged inpatient admissions for treatment and AE management[1]

Outpatient

- Sufficient staff and hours/days of clinic operations to support all aspects of CAR T cell delivery[1]
- Rooms or treatment areas must meet infection control standards for immunocompromised patients[1]
- Patient/caregiver education should be provided regarding monitoring for and identifying AEs, and appropriate next steps[1]
- Reliable workflow for the triaging of patients to the hospital in the event of an AE or other complication[1]
- Education of emergency department (ED)/outside hospital staff for potential management of CAR T cell therapy patients[1]

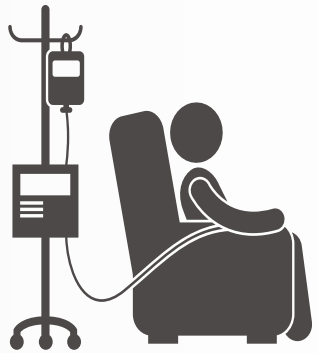
Inpatient administration may be appropriate for patients with increased risk of CRS, NT, or other toxicities[3]

AE, adverse event; CRS, cytokine release syndrome; ICU, intensive care unit; NT, neurotoxicity.

References: 1. Taylor L, et al. *Clin J Onc Nurs*. 2019;23(2):20-26. **2.** McGuirk J, et al. *Cytotherapy*. 2017;19:1015-1024. **3.** Yanez L, et al. *HemaSphere*. 2019;3:2(e186).

Administration Considerations

- Rooms or treatment areas must meet infection control standards for immunocompromised patients[2]
- Patient/caregiver education should be provided regarding monitoring for and identifying AEs, and appropriate next steps[2]
- Bed space in units should be reserved for potential inpatient admissions for CAR T cell-related AE management or other complications[2]
- Coordinated workflow for the triaging of patients to the hospital in the event of an AE or other complication[2]
- Education of emergency department/outside hospital staff for potential management of CAR T cell therapy patients[2]
- Hours and days of clinic operations must be sufficient to support all aspects of CAR T cell infusion[2]



AE, adverse event.

Reference: Taylor L, et al. *Clin J Onc Nurs*. 2019;23(2):20-26.

Post-infusion Monitoring

The practice of inpatient versus outpatient monitoring varies, depending on physician discretion, institutional guidelines, and CAR T cell products[1]

- Patients must remain within close proximity to the CAR T cell therapy treatment center for at least 2 weeks following infusion to ensure quick access to care, regardless of whether the patient received the CAR T cell therapy as an inpatient or outpatient[2,3]
- Depending on the patient, product, and center, inpatient monitoring may be required for a period of time[1,4]

- Under certain circumstances, outpatient administration and monitoring may be appropriate per the treating physician's discretion[1]
  - When this occurs, patients are usually observed in the treating center for a few hours after the CAR T cell therapy infusion to monitor for acute reactions; if none occur, they are permitted to leave the treatment center[4]
  - Hospitalization may be necessary if toxicities develop[4]

References: 1. Brudno JN, Kochenderfer JN. *Blood Rev.* 2019:34:45-55. **2.** US Food and Drug Administration. Accessed June 27, 2025. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor **3.** Neelapu SS, et al. *Nat Rev Clin Oncol.* 2018;15(1):47-62. **4.** Maus MV, Levine BL. *Oncologist.* 2016;21:608-617.

Post-CAR T Monitoring Considerations

The following is an example of a treatment center's post-infusion monitoring recommendations. Monitoring recommendations may vary across patients, products, and centers[1,2]

CAR T infusion

1st week	2nd week	After 2 weeks	Long-term
Daily appointments at the CAR T cell therapy treatment center to monitor side effects	**Less frequent** appointments. Side effects are still common during this time, and it is important that patients continue to be closely monitored for side effects and come to scheduled appointments	If appropriate, patients that are stable may return to their primary hematologist/oncologist	Perform physical exam, blood tests, image scans (PET or CT), bone marrow aspiration and biopsy, as appropriate **Life-long monitoring for secondary malignancies**

Contact physician immediately if:[3]

*Other symptoms not included here may also require immediate medical attention.

Temperature ≥100.4°F (38°C)

Black or bloody stool, rectal bleeding, blood in urine

Headache that does not improve, blurred vision, dizziness

Coughing up/vomiting blood, nosebleed that does not stop with pressure or ice

Difficulty breathing

Tremors, confusion, loss of balance, trouble speaking, seizures

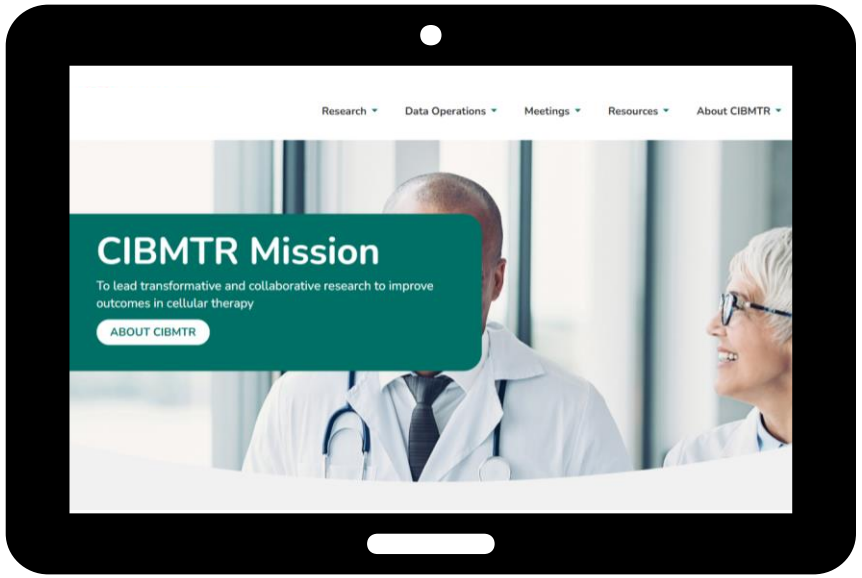
CT, computed tomography; PET, position emission tomography.

References: 1. Memorial Sloan Kettering Cancer Center. CAR T Cell Therapy A Guide for Adult Patients & Caregivers. https://www.mskcc.org/cancer-care/patient-education/car-cell-therapy-guide-adult-patients-caregivers. Accessed July 8, 2020. **2.** US Food and Drug Administration. Accessed June 27, 2025. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor **3.** Dana-Farber Institute. What Are The Side Effects of CAR T-Cell Therapy? Accessed October 20, 2021. https://blog.dana-farber.org/insight/2017/08/what-are-the-side-effects-of-car-t-cell-therapy.

Patient Registry and Data Capture

The CIBMTR Cellular Therapy Registry:

- Offers a platform for standardized, comprehensive data collection
  - After infusion, data captured at 3 months, 6 months, 1 year, and yearly thereafter



- Aligns with FDA regulatory recommendations to capture relevant CAR T cell–associated toxicities
  - Specific outcomes captured include CRS, neurotoxicities, neutrophil and platelet recovery, hypogammaglobulinemia, severe infections, nonhematologic grade 4 toxicities, death from any cause
  - Event-driven forms can be used to report subsequent neoplasms and pregnancies

CIBMTR, Center for International Blood and Marrow Transplant Research; CRS, cytokine release syndrome; FDA, US Food and Drug Administration

Reference: Lee DW, et al. *Biol Blood Marrow Transplant*. 2019;25:625-638.

Collaboration Between Non-CAR T Hematology Practitioners and Treating Institutions

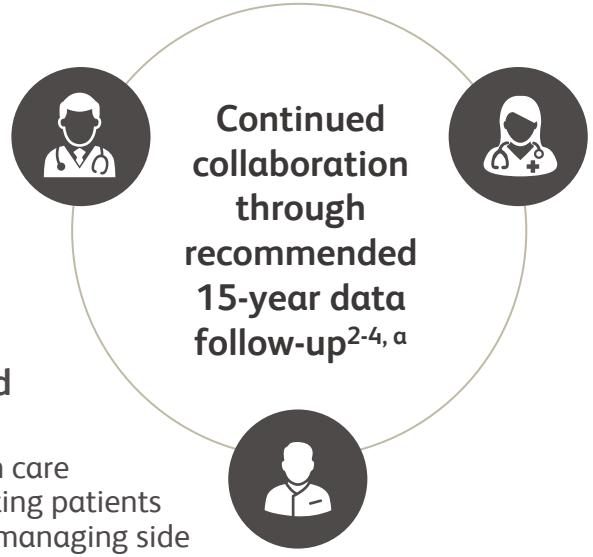
Patients will be co-managed by the primary hematologist and CAR T specialist leading up to infusion and following the initial post-infusion monitoring period. Care can then be transitioned back to the primary hematologist[1]

Non-CAR T Hematologist/ Oncologist

Refers patients for CAR T cell therapy[1]

Nurses, APPs, and Pharmacy Staff

Have a critical role in care coordination, educating patients and caregivers, and managing side effects including potential long-term effects[2,3,5]



CAR T Specialist

The treating provider at a qualified treatment facility[1]

Example topics of discussion for referring physicians and CAR T cell treatment sites when coordinating patient care

- ✓ Appropriate bridging therapy
- ✓ Washout periods pre-apheresis and pre-lymphodepletion
- ✓ Timing and coordination of patient care at each institution after CAR T cell infusion
- ✓ Methods of efficient communication between practices

[a]Patients should also be monitored in accordance with any applicable product-specific labeling.
APP, advanced practice providers.

References: 1. Beaupierre A, et al. *Clin J Oncol Nurs.* 2019;23:27-34. **2**. Beaupierre A, et al. *J Adv Pract Oncol.* 2019;10(suppl 3):29-40. **3**. Yakoub-Agha I, et al. *Haematologica.* 2020;105(2):297-316. **4**. US Food and Drug Administration. Accessed September 8, 2025. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-investigating-serious-risk-t-cell-malignancy-following-bcma-directed-or-cd19-directed-autologous **5.** Hayden PJ, et al. *Ann Oncol.* 2021;33(3):259-275.

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Caregiver Involvement and Support

Caregivers are an integral component of the patient care team during the post-infusion monitoring period, particularly in the outpatient setting[1,2]

Caregivers should be included in informed consent discussions, education, and all clinic visits[1]

Social workers may be needed to assist with lodging, psychosocial support, transportation, and family leave paperwork[1]

Key points to communicate to caregivers[1-3]

- Need for a reliable caregiver 24 hours a day for at least 2 weeks following CAR T cell infusion
- Staying close to the treatment center for at least 2 weeks following infusion (as instructed by the CAR T cell clinical care team)
- Monitor for signs/symptoms of CRS, NT, and other CAR T cell-related adverse events and take appropriate next steps (as instructed by the CAR T cell clinical care team)

CRS, cytokine release syndrome; NT, neurotoxicity.

References: 1. Taylor L, et al. *Clin J Onc Nurs*. 2019;23(2):20-26. **2.** Perica K, et al. *Biol Blood Marrow Transplant*. 2018;24(6):1135-1141. **3.** US Food and Drug Administration. Accessed June 27, 2025. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor

Caregivers Provide Practical, Medical, and Emotional Support

Practical

- Transportation to and from appointments
- Support with insurance and financial issues
- Preparing and handling food safely
- Tidying living spaces
- Discussing updates on patient condition with friends and family
- Managing visitations

Medical

- Gather information from CAR T team
- Administer medications and record timing as instructed by healthcare team
- Measure and record patient temperature every 4 hours while awake
- Keep written record of fluid intake
- Venous catheter care
- Monitor for and report any new symptoms or changes in patient condition especially those consistent with CRS and NT
- Know when and who to contact for medical help in an emergency

Emotional

- Observing and responding to moods and feelings of patient
- Communicating and listening to patient
- Learning and understanding needs and decisions
- Prepared to contact healthcare team or social worker if they're worried about patient emotional state

CRS, cytokine release syndrome; NT, neurotoxicity.

Reference: Memorial Sloan Kettering Cancer Center. CAR T Cell Therapy A Guide for Adult Patients & Caregivers. https://www.mskcc.org/cancer-care/patient-education/car-cell-therapy-guide-adult-patients-caregivers. Accessed July 8, 2020.

Summary

The CAR T cell patient journey with inpatient or outpatient administration has many similarities, except in infusion location[1]

The setting of CAR T cell therapy administration is decided by the treating physician based on a number of factors; some patients are suitable for outpatient administration[1]

Post-infusion, patients must return to the infusion center for frequent follow-up and may return to their regular physician's clinic or primary hematologist for long-term monitoring, per the CAR T treating institution's guidelines or CAR T physician's guidance[2,3]

Caregivers are required for post-infusion monitoring to provide medical, practical, and emotional support[3]

References: 1. Gatwood K, et al. *Clin Hematol Int.* 2024;6(2):11-20. **2.** US Food and Drug Administration. Accessed June 27, 2025. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor **3.** Memorial Sloan Kettering Cancer Center. CAR T Cell Therapy A Guide for Adult Patients & Caregivers. https://www.mskcc.org/cancer-care/patient-education/car-cell-therapy-guide-adult-patients-caregivers. Accessed August 26, 2025.

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We hope you found it informative and educational

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