



Outpatient Monitoring

CAR T Cell Therapy in the Outpatient Setting

Outpatient infusion and monitoring may improve CAR T cell therapy access¹



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^{b,2}

- 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 may be appropriate for treatment in the outpatient setting^{2,4}

^aThis assumes a setting-of-care-agnostic product label. ^bThe decision of the CAR T cell therapy administration setting lies with the treating physician.

AE, adverse event; HCP, healthcare provider.

References: 1. Bachier CR, et al. Abstract 8037. Presented at 2020 ASCO Virtual Scientific Program. 2. Yanez L, et al. *HemaSphere*. 2019;3:2(e186). 3. Smith S, Essell J. *J Clin Pathways*. 2018;4(8):42-47. 4. Gust J, et al. *Cancer Discov*. 2017;7(12):1404-1419.

CAR T Academy: Outpatient Monitoring

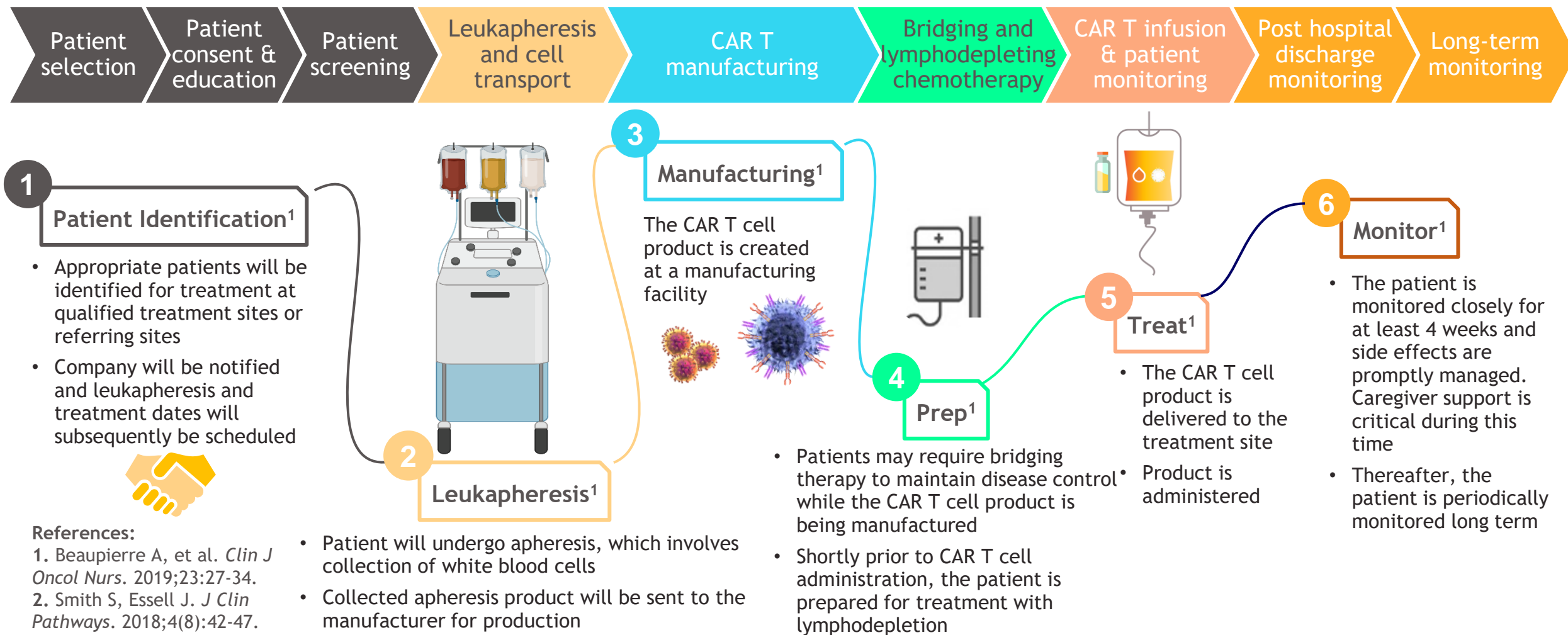


01 Patient Experience

02 Importance of a Caregiver

Patient Journey Through the CAR T Cell Therapy Process

The **steps of the CAR T cell process** can be the same between **outpatient** and **inpatient** settings^{1,2}



References:

1. Beupierre A, et al. *Clin J Oncol Nurs*. 2019;23:27-34.
2. Smith S, Essell J. *J Clin Pathways*. 2018;4(8):42-47.

The CAR T Cell Infusion Setting

Factors to Consider When Determining CAR T Cell Infusion Settings¹

- 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

- Every CAR T cell therapy program requires the ability to:
 - Safely administer CAR T cell therapy¹
 - Properly monitor and manage patients before, during, and following treatment²
- Treating physicians must determine the setting in which to safely deliver CAR T cell therapy¹
- CAR T cell therapy is typically infused in the inpatient setting; however, ambulatory infusion is becoming increasingly common¹

AE, adverse event.

References: 1. Taylor L, et al. *Clin J Onc Nurs*. 2019;23(2):20-26. 2. 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 management¹
- Compliance with standards for infection control required for cell therapy¹
- Accessibility to ancillary services involved in the care of patients treated with CAR T cell therapy²
- Consideration toward inpatient bed management due to potential prolonged inpatient admissions for treatment and AE management¹



Outpatient

- Sufficient staff and hours/days of clinic operations to support all aspects of CAR T cell delivery¹
- Rooms or treatment areas must meet infection control standards for immunocompromised patients¹
- Patient/caregiver education should be provided regarding monitoring for and identifying AEs, and appropriate next steps¹
- Reliable workflow for the triaging of patients to the hospital in the event of an AE or other complication¹
- Education of emergency department (ED)/ outside hospital staff for potential management of CAR T cell therapy patients¹

Inpatient administration may be appropriate for patients with increased risk of CRS, NT, or other toxicities³

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



Some hospitals have moved to outpatient infusion for some CAR T cell therapy trials¹

- Rooms or treatment areas must meet infection control standards for immunocompromised patients²
- Patient/caregiver education should be provided regarding monitoring for and identifying AEs, and appropriate next steps²
- Bed space in units should be reserved for potential inpatient admissions for CAR T-related AE management or other complications²
- Coordinated workflow for the triaging of patients to the hospital in the event of an AE or other complication²
- Education of emergency department/outside hospital staff for potential management of CAR T patients²
- Hours and days of clinic operations must be sufficient to support all aspects of CAR T cell infusion²

AE, adverse event.

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

Post-infusion Monitoring



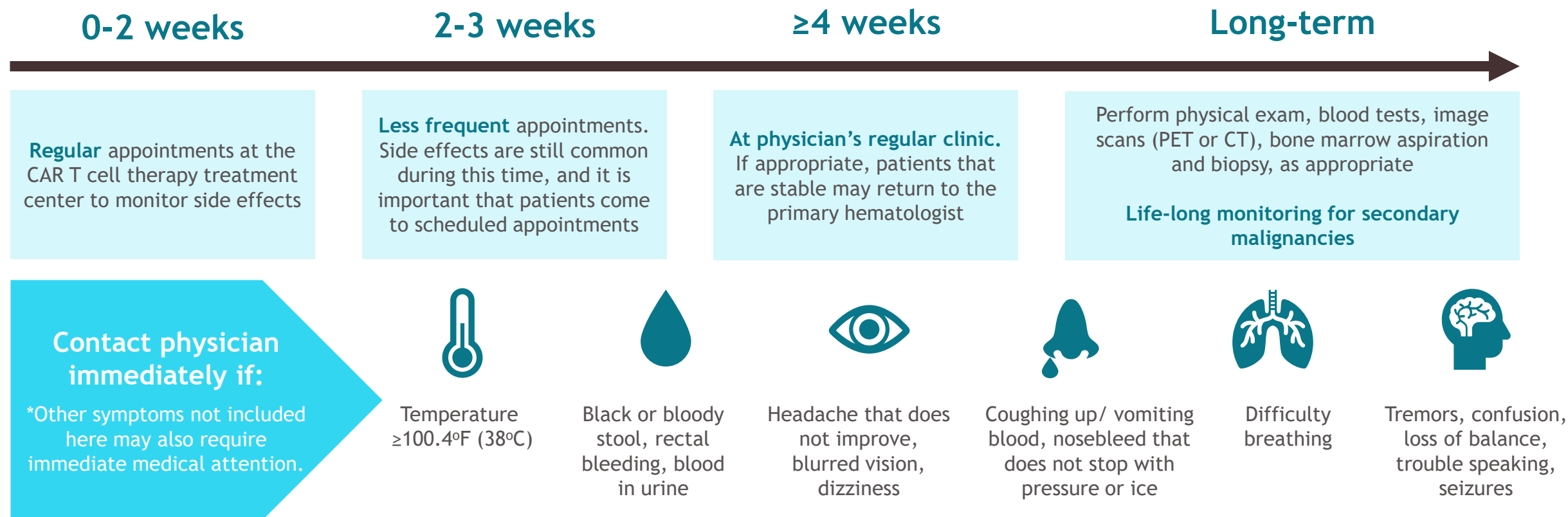
The practice of inpatient versus outpatient monitoring varies, depending on physician discretion, institutional guidelines, and CAR T cell products¹

- Patients must remain within close proximity to the treatment center for at least 4 weeks to ensure quick access to care, regardless of whether the patient received the CAR T cell therapy as an inpatient or outpatient²
- Depending on the patient, product, and center, inpatient monitoring may be required for a period of time^{1,3}
- Under certain circumstances, outpatient administration and monitoring may be appropriate per the treating physician's discretion¹
 - 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 center⁴
 - Hospitalization may be necessary if toxicities develop⁴

References: 1. Brudno JN, Kochenderfer JN. *Blood Rev.* 2019;34:45-55. 2. Taylor L, et al. *Clin J Onc Nurs.* 2019;23(2):20-26. 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



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. National Institutes of Health. DailyMed. Accessed October 20, 2021. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9b70606e-b99c-4272-a0f1-b5523cce0c59>. 3. National Institutes of Health. DailyMed. Accessed October 20, 2021. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aad3ba54-dfd3-4cb3-9e2b-c5ef89559189>. 4. National Institutes of Health. DailyMed. Accessed October 20, 2021. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=594bb413-af3b-4b97-afb3-bfe2b174f2ed>. 5. National Institutes of Health. DailyMed. Accessed October 20, 2021. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b90c1fe7-f5cc-464e-958a-af36e9c26d7c>. 6. National Institutes of Health. DailyMed. Accessed October 20, 2021. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a16108c2-7ca7-45af-965e-54bda4713022>. 7. 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>.

CAR T Academy: Outpatient Monitoring



01 Patient Experience

02 Importance of a Caregiver

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

- Caregivers should be included in informed consent discussions, education, and all clinic visits
- Social workers may be needed to assist with lodging, psychosocial support, transportation, and family leave paperwork

Key points to communicate to caregivers

- Need for a reliable caregiver 24 hours a day for at least 4 weeks following CAR T cell infusion
- Staying close to the treatment center for at least 4 weeks (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



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.

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

Thank you for completing this module of CAR T Academy

We hope you found it informative and educational



- Follow this link to download a printable acknowledgment of completion:
<https://www.car-t-academy.com/pdf/car-t-academy-outpatient-monitoring-acknowledgment.pdf>
– NOTE: Completion of CAR T Academy modules does not qualify as CME or any other type of accreditation
- For more information and access to other CAR T Academy modules, please visit:
<https://www.car-t-academy.com>