Bristol Myers Squibb®

CAR T ACADEMY

Long-term Follow-up of Patients Receiving CAR T Cell Therapy

The CAR T Academy Modules are intended to provide a high-level overview of select adverse events and are not meant to be a comprehensive discussion of all adverse events contemplated for CAR T cell therapy.

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 the 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.

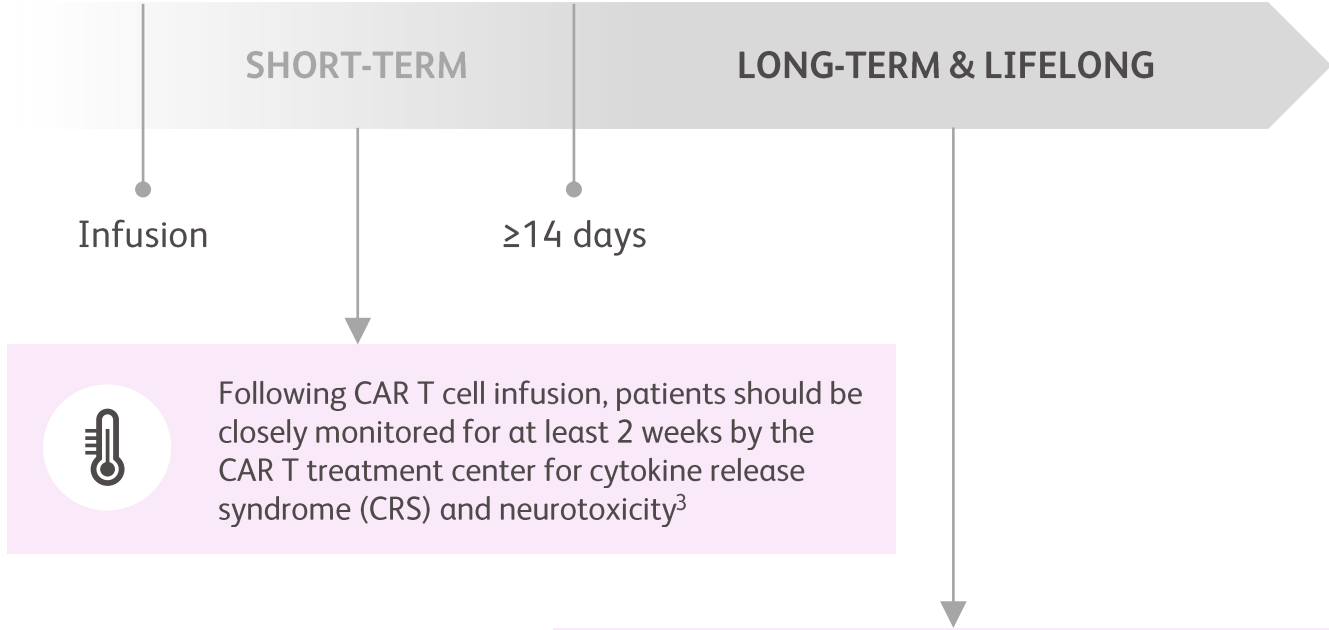
References: 1. Beaupierre A, et al. *J Adv Pract Oncol.* 2019;10(Suppl 3):29-40. **2.** Beaupierre A, et al. *Clin J Oncol Nurs.* 2019;23:27-34. **3.** McGuirk J, et al. *Cytotherapy.* 2017;19(9):1015-1024. **4.** Qayed M, et al. *Cytotherapy.* 2022;S1465-3249(22)00641-7. **5.** US Food and Drug Administration. 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.

Need for Long-term Follow-up

CAR T cells may persist for multiple years in some patients, underscoring the need for long-term monitoring for late effects of treatment[1,2]

Long-term patient monitoring begin at 15 days post infusion, or upon resolution of short-term toxicities[3]

Patients should be monitored life-long for the development of secondary malignancies[3]



Refer to the CRS and Neurotoxicity module for more information on short-term monitoring

References: 1. Hartmann J, et al. *EMBO Mol Med.* 2017;9(9):1183-1197.
2. Boyiadzis MM, et al. *J Immunother Cancer.* 2018;6(1):1-12. **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
4. Hayden PJ, et al. *Ann Oncol.* 2021;33(3):259-275.

Transfer Back to the Referring Provider

After at least 2 weeks, or when toxicities resolve, patients can be transferred back to the referring provider.

Recommended Information to Be Shared With the Referring Provider

- ✓ Results of all baseline tests performed prior to CAR T cell infusion
- ✓ Clinical summary of the patient's progress, including information regarding the risk for adverse events (AEs) and recommended interventions
- ✓ Current disease staging information
- ✓ Information regarding specific laboratory orders and how often they should be performed
- ✓ Recommendations for monitoring late-onset cytopenias
- ✓ Recommendations for possible administration of blood products, if necessary
- ✓ Medication list (eg, prophylactic antibiotics and antiviral medications)
- ✓ CAR T cell product information (United States Prescribing Information [USPI] and medication guide)
- ✓ Copy of patient wallet card listing symptoms that may occur post-treatment
- ✓ List of approximate dates when the patient should follow up with the treating center

Reference: Beaupierre A, et al. *Clin J Oncol Nurs.* 2019;23(2):27-34.

CAR T Academy: Considerations for Long-term Follow-up

01: POST-TREATMENT COMPLICATIONS

02: RELAPSE

03: PSYCHOSOCIAL FACTORS

04: LOGISTICAL CONSIDERATIONS

05: REGISTRY

The Physiologic Effects of Post–CAR T Cell Therapy

The physiologic effects of CAR T cell therapy are becoming better understood as the pool of patients who receive such therapy grows. Several interventions can be utilized to address the physiologic effects of CAR T cell therapy, which underscores the need for long-term monitoring to ensure long-term patient safety

Example Physiologic Effects

Cytopenias

Infections

Hypogammaglobulinemia

Secondary malignancies

Late neurologic toxicities

Fatigue

Infertility[a]

[a]Infertility is not a known physiologic effect of commercial CAR T cell therapies.

Reference: Buitrago J, et al. *Clin J Onc Nurs.* 2019;23(2):42-48.

Cytopenias

Understanding the Risk

- Cytopenias including anemia, thrombocytopenia, leukopenia, and neutropenia are common acute toxicities following CAR T cell therapy

Several studies also demonstrate chronic cytopenias lasting ≥3 months after CAR T cell infusion

Approximately **15%** of patients with **B cell lymphoma** were found to have grade 3/4 cytopenias at ≥3 months after CAR T cell infusion

According to one long-term follow-up study, clinically significant cytopenias were found in **16%** of patients with **B-cell malignancies** in CR after treatment with CD19 CAR T cell therapy and lasted for **15-22 months after infusion**

Grade ≥3 neutropenia (in **20%**) and thrombocytopenia (in **47%**) have been observed in patients with **multiple myeloma** at 100 days after CAR T cell infusion

CR, complete remission.

Reference: Cappell KM, Kochenderfer JN. *Nat Rev Clin Oncol.* 2023 Jun;20(6):359-371.

Cytopenias (cont.)

Understanding the Risk

- Evidence suggests that CAR T cell therapy can induce myelosuppression via cytokine-mediated and perhaps other mechanisms. Lymphodepleting chemotherapy administered prior to CAR T cell therapy may also induce myelosuppression[1]
- More severe and prolonged cytopenias have been observed in patients with ALL compared to patients with large cell lymphomas likely due to ALL being bone marrow-based and having more baseline cytopenias[2]

The risk of cytopenias is associated with the following[3]:

- Higher-grade CRS
- Multiple previous lines of therapy
- Receipt of allogeneic HSCT ≤1 year prior to CAR T cell infusion
- Baseline cytopenia
- Presence of bone marrow malignancy

ALL, acute lymphoblastic leukemia; HSCT, hematopoietic stem cell transplant.

References: 1. Brudno JN, Kochenderfer JN. *Blood.* 2016;127(26):3321-3330. **2.** Dahunsi D. *Clin Hematol Int.* 2025 Mar 26;7(1):47-54. **3.** Cappell KM, Kochenderfer JN. *Nat Rev Clin Oncol.* 2023 Jun;20(6):359-371.

Cytopenias (cont.)

Monitoring and Follow-up Care

- Monitor blood counts weekly through 60 days post-infusion or as indicated until recovery[1]
- Provide transfusion and/or growth factor support to patients with severe cytopenias, when appropriate.[1] Support may include:
  - Red blood cell transfusions[2]
  - Platelet transfusions[2]
  - Filgrastim[2]

Note: Institutional and product guidelines may vary.[3]

References: 1. Buitrago J, et al. *Clin J Onc Nurs.* 2019;23(2):42-48. **2.** Brudno JN, Kochenderfer JN. *Blood.* 2016;127(26):3321-3330. **3.** Brudno JN, Kochenderfer JN. *Blood Rev.* 2019;34:45-55.

Infections

Understanding the Risk

- Infections following CAR T cell therapy are common and can be severe or life-threatening[1]
- Infections are the second most common cause of non-cancer-related mortality within the first year after cancer diagnosis. Most of these deaths are caused by influenza and pneumonia[2]

- Infections following CAR T cell infusion may include, but are not limited to Bacteremia, *Salmonella,* urinary tract infections, and viral infections such as influenza, respiratory syncytial virus, herpes zoster virus, Epstein-Barr virus, and cytomegalovirus[3,4]
- The incidence of severe infections is much greater within the first month following CAR T cell infusion than after the first month and the incidence decreases over time[5]
- A long-term follow-up study of 43 patients with B cell malignancies treated with CAR T cell therapy found that 9% required hospital admissions for infections at >6 months after CAR T cell therapy with a median follow-up of 42 months[5]

Factors that may be associated with increased risk for infection include[3]:

- Type of malignancy
- ≥4 prior lines of therapy
- Higher CAR T cell dose
- Higher grade of CRS

References: 1. Shahid Z et al. *Transplant Cell Ther.* 2024;30(10):955-969. **2.** Kamboj M, et al. *J Clin Oncol.* 2024 May 10;42(14):1699-1721. **3.** Hill JA, et al. *Blood.* 2018;131(1):121-130. **4.** Brudno JN, Kochenderfer JN. *Blood.* 2016;127(26):3321-3330. **5.** Cappell KM, Kochenderfer JN. *Nat Rev Clin Oncol.* 2023 Jun;20(6):359-371.

Infections (cont.)

Monitoring and Follow-up Care

- Closely monitor patients who become febrile after infusion for signs of infection. Keep in mind that fever may also be a sign of CRS[1]
- Treatment of neutropenia and/or bacterial prophylaxis at onset of severe neutropenia may mitigate or prevent infections[2]
- Both expert consensus and evidence-based guidelines have been developed to support revaccination after CAR T cell therapy[3,4]

Example Guidance from ASTCT Committee

To support patients at risk for infection (eg, immunosuppression, presence of cytopenias) consider whether the following are appropriate[5,6]:

- **Antiviral prophylaxis** for ≥6 months after CAR T cell therapy
- **Antibacterial and antifungal prophylaxis** as needed (eg, in high-risk patients, patients with prolonged neutropenia)

Common practice is for centers to extrapolate prophylaxis recommendations from HSCT experiences and expert opinion, although there may be variability in agent, timing, and duration.[5]

Follow institutional guidance and recommendations from the CAR T cell treatment center for AE management in patients after CAR T cell therapy.

ASTCT, American Society for Transplantation and Cellular Therapy.

References: 1. Brudno JN, Kochenderfer JN. *Blood Rev.* 2019:34:45-55. **2.** Dahunsi D. *Clin Hematol Int.* 2025 Mar 26;7(1):47-54. **3.** Kamboj M, et al. *J Clin Oncol.* 2024 May 10;42(14):1699-1721. **4.** Reynolds G, et al. *Transpl Infect Dis.* 2023 Nov;25 Suppl 1(Suppl 1):e14109. **5.** Shahid Z et al. *Transplant Cell Ther.* 2024;30(10):955-969. **6.** Hayden PJ et al. *Ann Oncol.* 2022;33(3):259-275.

Infections (cont.)

Vaccination

- Although responses to vaccines may be lower in patients that have received CAR T cell therapy compared to immunocompetent individuals, vaccination may reduce infection frequency and severity[1,2]

Example Guidance from ASTCT Committee

To prevent infections in patients that received CAR T cell therapy, consider whether the following are appropriate[2]:

- **3 months** after CAR T cell therapy: consider seasonal influenza vaccine and SARS-CoV-2 vaccines
- **6 months** after CAR T cell therapy: consider inactivated vaccines
- **1 year** after CAR T cell therapy: consider live and non-live adjuvant vaccines

Example Vaccination Recommendations per ASTCT Committee[2]

	Months after CAR T cell therapy					
	>3 mo	>6 mo	>8 mo	>10 mo	>12 mo	>18 mo
Influenza	✓					
RSV	✓					
SARS-CoV	✓					
Pneumococcus		✓	✓	✓		
Diphtheria, tetanus, and acellular pertussis		DTap	Td	Td		
Hepatitis A		✓			✓	
Hepatitis B		✓	✓		✓	
Shingrix					✓	✓

Follow institutional guidance and recommendations from the CAR T cell treatment center for AE management in patients after CAR T cell therapy.

Dtap, diphtheria, tetanus, and acellular pertussis; RSV, respiratory syncytial virus; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; Td, tetanus-diphtheria.

References: 1. Hayden PJ et al. *Ann Oncol.* 2022;33(3):259-275. **2.** Shahid Z et al. *Transplant Cell Ther.* 2024;30(10):955-969.

Hypogammaglobulinemia

Understanding the Risk

- B cells produce antibodies that recognize foreign antigens and protect against infection[1]
- CAR T cells can kill healthy B cells in addition to malignant B cells (on-target, off-tumor effect)[1]
- This activity can lead to B-cell aplasia, chronic immunodeficiency, and hypogammaglobulinemia (IgG <400 mg/dL)[1]
- B-cell aplasia may persist in ongoing responders; it was observed for up to 1 and 2 years[2]:
  - In **50%** and **25%** of patients with **LBCL**, respectively
  - In **71%** and **59%** of patients with **B-ALL**, respectively

Monitoring and Follow-up Care

- Check immunoglobulin G (IgG) levels monthly[3]
- Consider monthly immunoglobulin infusions for patients who develop frequent infections, especially those with IgG <400 mg/dL[1]
- Given how long this complication can last, IgG replacement may be necessary[1]

Note: Institutional and product guidelines may vary[1]

B-ALL, B-cell acute lymphoblastic leukemia.

References: 1. Buitrago J, et al. *Clin J Onc Nurs.* 2019;23(2):42-48. **2.** Puckrin R, Jamani K, Jimenez-Zepeda VH. *Eur J Haematol.* 2024;112(1):41-50. **3.** Callahan C, et al. *Clin J Onc Nurs.* 2019;23(2):35-41.

Secondary Malignancies

Understanding the Risk

- Because genetic alteration is used to create CAR T cells, there is a possibility that these products can cause insertional mutagenesis, resulting in secondary malignancies[1]
- Data from large-cohort follow-up studies indicate an incidence of secondary malignancies after CAR T cell infusion of **4-16%**[2]
- These incidences are not higher than expected given that all patients had a history of substantial chemotherapy exposure[2]
  - Additionally, risk for new cancers may be driven by factors such as previous chemotherapy and/or radiation exposure[2]

Monitoring and Follow-up Care

- Healthcare providers need to follow patients who receive CAR T cell therapy life-long for secondary malignancies, per FDA requirements[3-10]
  - In the event that a secondary malignancy occurs:
    - Notify the CAR T cell therapy manufacturer[3-10]
    - Report the event to the FDA via MedWatch[4-10]
- Secondary malignancies should be treated per disease-specific protocols[11]

FDA, US Food and Drug Administration.

References: 1. Buitrago J, et al. *Clin J Onc Nurs.* 2019;23(2):42-48. **2.** Cappell KM, Kochenderfer JN. *Nat Rev Clin Oncol.* 2023 Jun;20(6):359-371. **3.** Beaupierre A, et al. *J Adv Pract Oncol.* 2019;10(Suppl 3):29-40. 4. National Institutes of Heath. DailyMed. Accessed July 17, 2025. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=594bb413-af3b-4b97-afb3-bfe2b174f2ed. **5.** National Institutes of Health. DailyMed. Accessed July 17, 2025. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b90c1fe7-f5cc-464e-958a-af36e9c26d7c. 6. National Institutes of Health. DailyMed. Accessed July 17, 2025. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aad3ba54-dfd3-4cb3-9e2b-c5ef89559189. **7.** National Institutes of Health. DailyMed. Accessed July 17, 2025. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9b70606e-b99c-4272-a0f1-b5523cce0c59. **8.** National Institutes of Health. DailyMed. Accessed July 17, 2025. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a16108c2-7ca7-45af-965e-54bda4713022 **9**. National Institutes of Health. DailyMed. Accessed July 17, 2025. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7d040b91-3fb8-41db-ba7f-60a36f06e2c2 **10.** National Institutes of Health. DailyMed. Accessed July 17, 2025. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4fef6986-b988-45e4-8c20-b14f0ef1f538 **11.** Cordeiro A, et al. *Biol Blood Marrow Transplant.* 2020;26(1):26-33.

Late Neurologic Toxicities

Understanding the Risk

- Neurologic toxicities can arise following infusion, including seizures, weakness, confusion, aphasia, and coordination problems[1]
- ICANS is typically an early complication arising during the first **1-2 weeks** after CAR T cell infusion, corresponding to the **period of peak CAR T cell activation and expansion**[2]
  - However, up to 10% of patients experience delayed onset ICANS with confusion and seizures occurring as late as 3-4 weeks after infusion[2]
  - Case reports have also described severe and even fatal ICANS occurring as late as 6-9 months after treatment[2]

Monitoring and Follow-up Care

- Given the potential for neurologic toxicity, patients should not drive for at least 2 weeks post-infusion[3]
- Neuroimaging and cerebrospinal fluid analysis should be performed to exclude other etiologies (eg, stroke, infection)[2]
- Seizure prophylaxis (eg, levetiracetam) may be prescribed to prevent seizure[1]
- Patient caregivers should be educated about possible neurologic toxicities and monitor for any changes so they can be immediately addressed[1]

ICANS, immune effector cell-associated neurotoxicity syndrome.

References: 1. Buitrago J, et al. *Clin J Onc Nurs.* 2019;23(2):42-48. **2.** Puckrin R, Jamani K, Jimenez-Zepeda VH. *Eur J Haematol.* 2024;112(1):41-50. **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.

Fatigue

Understanding the Risk

- Fatigue can be a common and difficult-to-manage side effect of CAR T cell therapy[1]
- In select CAR T cell clinical trials, the incidence of fatigue ranged from **25% to 53%**[2-6]
- Fatigue has been reported to resolve in some patients within 4-6 weeks post-infusion[1]

Monitoring and Follow-up Care

- Rule out any contributing factors (eg, anemia, hypothyroidism)[7]
- Steroids should be avoided due to potential T cell suppression that might limit the activity of CAR T cell therapy[1]
- Nonpharmacologic interventions include exercise, yoga, meditation, Pilates, and massage therapy[1]

References: 1. Buitrago J, et al. *Clin J Onc Nurs.* 2019;23(2):42-48. **2.** Munshi NC, et al. *N Engl J Med* 2021;384:705-16. **3.** Abramson JS, et al. *Lancet.* 2020;396(10254):839-852. **4.** Locke FL, et al. *Lancet Oncol.* 2019;20(1):31-42. **5.** Schuster SJ, et al. *N Engl J Med.* 2019;380(1):45-56. **6.** Wang M, et al. *N Engl J Med.* 2020;382(14):1331-1342. **7.** American Cancer Society. Accessed August 10, 2021. https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/fatigue/what-is-cancer-related-fatigue.html.

Infertility

Understanding the Risk[1]

- Fertility may be compromised by older age and/or the gonadotoxic effects of chemotherapy, radiation, and HCT
- Implications of CAR T cell therapy on fertility are not well understood, and institutional policies may vary widely[a]
  - Further research is needed into the reproductive considerations of CAR T cell therapy and the potential impact on a developing fetus
- The dose of cyclophosphamide in LDC is believed to pose minimal risks to fertility in men and women
- Despite these potential risks, successful pregnancies have been reported in small numbers of CAR T cell recipients

Monitoring and Follow-up Care

- As with other cancer treatments, fertility preservation options should be discussed with patients with child-bearing potential prior to CAR T cell therapy[1]
- Pregnancy and effective contraception should be discussed as part of the treatment plan, particularly for patients who are adolescents or young adults[2]
  - The use of effective contraception is recommended for at least 6-12 months after LDC due to the risk of teratogenicity[1,b]

[a] Based on a survey of 66 cellular therapy centers. [b] There is insufficient data to recommend an optimal time to conceive a child after lymphodepleting chemotherapy and CAR T cell infusion.

References: 1. Puckrin R, Jamani K, Jimenez-Zepeda VH. *Eur J Haematol.* 2024;112(1):41-50. **2.** Callahan C, et al. *Clin J Onc Nurs.* 2019;23(2):35-41.

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Restaging Scans

After a patient undergoes CAR T cell infusion, periodic follow-up is necessary to restage disease and determine the response to treatment

Restaging PET/CT scans are typically performed:

- 30 to 90 days post-infusion
- Every 3 months for the first 2 years post-infusion

Reimaging should also be performed for patients with signs/symptoms of disease recurrence (such as unexplained fever or chills, new pain, lymphadenopathy)

PET/CT, positron emission tomography/computed tomography

Reference: Beaupierre A, et al. *Clin J Oncol Nurs.* 2019;23(2):27-34.

Managing Relapse

- **Relapse can occur for many reasons[1,2]:**
  - Loss of the antigen of interest
  - Lack of persistence or function of CAR T cells
  - CAR T cells may become exhausted, thereby limiting their anticancer effects
  - Tumors can develop compensatory mechanisms that lead to immune evasion

In certain settings, consolidation therapy with allogeneic stem cell transplantation or participation in a clinical trial (if eligibility criteria are met) can be considered[3,4]

When relapse occurs, alternative treatment strategies specific to the patient's disease are necessary (eg, chemotherapy, targeted therapy, clinical trial, etc)[4]

References: 1. Perica K, et al. *Biol Blood Marrow Transplant.* 2018;24:1135-1141. **2.** Abramson JS, et al. *Am Soc Clin Oncol Educ Book.* 2019;39:446-453. **3.** Beaupierre A, et al. *Clin J Oncol Nurs.* 2019;23(2):27-34. **4.** Byrne M, et al. *Biol Blood Marrow Transplant.* 2019;25(11):e344-e351.

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Psychosocial Effects of CAR T Cell Therapy

Although response to CAR T cell therapy is associated with improvements in quality of life, screening and support for mental health disorders remain an important part of routine care[1]

Patients may experience[2]:

Heightened anxiety or fear of recurrence

Changes in physical functioning that impact quality of life

Other mental stressors associated with the therapeutic process (eg, consistent caregiver support, financial concerns) resulting in compromised coping

References: 1. Puckrin R, Jamani K, Jimenez-Zepeda VH. *Eur J Haematol.* 2024;112(1):41-50. **2.** Buitrago J, et al. *Clin J Onc Nurs.* 2019;23(2):42-48.

Strategies for Managing Psychosocial Effects

Survivorship programs are resources that can provide:

- Ongoing communication between patients and treating providers
- Interventions that enable patients to recognize and manage anxiety and that promote positive coping
- Opportunities to engage with other survivors through support groups

- Additional avenues of support can include:
  - Social workers, chaplains, clinical psychologists/psycho-oncologists, and community-based organizations
  - Online forums (eg, social media, online support groups specifically for patients who have received CAR T cell therapy)
- Ensuring adequate caregiver support may also prove beneficial

References: 1. Puckrin R, Jamani K, Jimenez-Zepeda VH. *Eur J Haematol.* 2024;112(1):41-50. **2.** Buitrago J, et al. *Clin J Onc Nurs.* 2019;23(2):42-48.

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Logistical Considerations for CAR T Cell Therapy

The total cost of CAR T cell therapy and all medical-related expenses is considerable[1,2]

Expenses may include:

- Emergency care or hospitalization for adverse events
- Follow-up appointments for disease and side effects monitoring
- Insurance-related expenses

Strategies for managing logistics[2]

Have transparent conversations with patients and caregivers about treatment costs upfront

Regularly assess for financial constraints and psychosocial sequelae like any other adverse event, and provide support as appropriate

Connect patients to financial assistance programs (where available)

References: 1. Perica K, et al. *Biol Blood Marrow Transplant.* 2018;24:1135-1141.
2. Buitrago J, et al. *Clin J Onc Nurs.* 2019;23(2):42-48.

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Patient Registry and Data Capture

The FDA recommends 15 years of observation for patients who receive CAR T cell therapies[1]

Center for International Blood and Marrow Transplant Research (CIBMTR)[1]

- CIBMTR launched a database dedicated to cellular therapy outcomes in 2016 that can be used to capture long-term data for patients who receive CAR T cells or other cellular therapies aside from hematopoietic stem cell transplantation
- 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
- Patients should also be monitored lifelong for the development of secondary malignancies

CRS, cytokine release syndrome; FDA, US Food and Drug Administration

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

Summary

Several physiologic effects can arise following CAR T cell therapy[1]

- Many of these may be successfully managed with prophylactic treatment, close monitoring, and prompt intervention, when necessary

Periodic imaging is necessary to determine the response to treatment, restage disease, and monitor for relapse[2]

- When relapse occurs, alternative disease-specific treatment strategies are necessary

Psychosocial effects and financial constraints associated with CAR T cell therapy should not be overlooked[1]

- Several avenues of support can help patients cope with these issues, including survivorship programs, support groups, etc

FDA recommends 15 years of observation and long-term AE reporting for patients who receive CAR T cell therapies[3]

- This can be accomplished by utilizing the CIBMTR Cellular Therapy Registry
- Patients should also be monitored lifelong for the development of secondary malignancies

Reference: 1. Buitrago J, et al. *Clin J Onc Nurs.* 2019;23(2):42-48. **2.** Beaupierre A, et al. *Clin J Oncol Nurs.* 2019;23(2):27-34. **3.** Lee DW, et al. *Biol Blood Marrow Transplant.* 2019;25:625-638.

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