

Billings Clinic Cancer Center CAR T-cell Practice Profile

From clinical trial site to commercial CAR T-cell therapy in the community

This article explores the approach of Billings Clinic Cancer Center to establishing the infrastructure to deliver CAR T-cell therapy in the community and its lessons learned.

Billings Clinic provides quality oncology specialty services to individuals in a vast geographic area and is one of the largest health systems in Montana. The hematologic cancer program provides exceptional patient care for patients living with leukemias, lymphomas, and multiple myeloma, who have access to a robust referral network and state-of-the-art treatment options. Billings Clinic Cancer Center is an autologous stem cell transplant center and recently received accreditation by the [Foundation for the Accreditation of Cellular Therapy](#) (FACT). FACT accreditation is a voluntary peer-reviewed process indicating Billings Clinic meets rigorous standards promoting high quality cellular therapeutic care.¹

In spring 2022, staff from Billings Clinic participated in a focus group to identify effective practices and lessons learned that can help other community cancer programs develop the infrastructure needed to bring CAR T-cell therapies to their communities.

CAR T-cell Clinical Trial

Chimeric antigen receptor (CAR) T-cell therapy is an innovative treatment for blood cancers that uses the patient's own T-cells that are genetically engineered with receptor proteins that bind to and kill cancer cells after being re-infused to the patient. Building on their existing FACT accreditation, in 2018 Billings Clinic

participated in a CAR T-cell clinical trial for the Cartesian Decartes-08 CAR T-cell product, the only trial of CAR T-cell therapy in Montana at that time. After mobilizing a multidisciplinary team and conducting a comprehensive risk assessment, a patient with multiple myeloma was enrolled in the trial in 2019.

The principal investigators for Billings Clinic were Carlos Silva, MD, Stem Cell Transplant Program Director and Jesus C. Fabregas, MD, Department Chair Hematology-Oncology. A dedicated multidisciplinary team participated in the preparation, implementation, care, staff training, and patient education during the trial, including the Lead Oncology Pharmacist, Nurse Clinician/Clinical and Collections Quality Manager, Cancer Center Director, Coding Advisor, Financial Counselor, and Hematology Navigator.

Implementation

As a stem cell transplant center, Billings Clinic leveraged existing policies and procedures, provider education, and collaborative

care models to mitigate risks and improve outcomes for the patient participating in the trial. All institutions administering CAR T-cell therapies must meet the standards set by the Food and Drug Administration's [risk evaluation and mitigation strategy](#) (REMS) in order to prepare for and reduce the risk of serious adverse events associated with side effects from the therapy.² Nicole West, RN, Nurse Clinician and Clinical and Collections Quality Manager describes how the comprehensive risk assessment and multidisciplinary approach ensured "that anybody who was coming in contact with that patient was going to be prepared."

Staff Education and Training

A key component of the staff training on CAR T-cell therapy were Grand Rounds sessions offered by Drs. Silva and Fabregas. Training sessions were recorded and available to staff on the internal learning management system. The training gave a detailed overview of the CAR T-cell therapy treatment roadmap, rationale for offering



CAR T-cell therapy, and evidence of effectiveness, providing details on clinical protocols for management of side effects.

Another integral component of staff education and training were detailed job aides that were integrated within Billings Clinic's clinical policies and procedures. Designed for the multidisciplinary team, these job aides included resources from the trial sponsor, clinical protocols, and the below staff education tools developed by Billings Clinic:

- An overview of clinical trial and key contact information for the clinical staff involved in the patient's care
- Critical alerts and protocols for patient emergency and ICU care, including inpatient admission diagnoses and workups for providers
- Product-specific training on cell collection, storage, and handling
- Pharmacy-specific requirements, including protocols for stocking medications to treat side effects as required by the FDA REMS protocol
- Clinical protocols for preparative chemotherapy and immune-effector cell re-infusion stages
- Assessment guide and grading system for cytokine release syndrome (CRS) and CRS-related encephalopathy syndrome (CRES) management

Systems Checks

The Billings Clinic team created prompts in the electronic health record (EHR) to alert healthcare staff of special orders and precautions related to the patient's therapy. For providers and pharmacists, an alert was created to signal that steroids should not be prescribed or administered without approval from study physicians, and instructions were available for administration of Tocilizumab to manage serious side effects.

Communication

Multidisciplinary communication with clinic administration, emergency department (ED), and ICU regarding the project background, patient identification, side effect management, and clinical protocols helped ensure that the patient received appropriate care. As part of the REMS protocol, the patient was provided with a wallet card to facilitate communication about common side effects and their management with other healthcare providers in an emergency. The study team even collaborated with management at the hotel the patient was staying at to ensure timely and accurate response if the patient required emergency medical care.

"Our goal was that... everyone was aware of the patient, what the patient's needs were, and how to properly treat the patient."

Lessons Learned and Unexpected Benefits

Although the CART-cell therapy clinical trial education and protocols were designed specifically for the patient with multiple myeloma participating in the trial, these systems were mobilized unexpectedly when a pediatric patient presented to the ED with delayed CRS after receiving CAR T-cell therapy elsewhere. Because of the multidisciplinary staff training and communication, nurses and providers were able to better serve the patient by understanding CAR T-cell treatment and management of side effects. West noted, "we started with getting all the stakeholders together,

making policy changes, and focusing on staff education and care coordination. Our goal was that if the patient arrived in the ED or the ICU, the inpatient oncology unit or infusion center, everyone was aware of the patient, what the patient's needs were, and how to properly treat the patient."

The Future of CAR T-cell Therapy at Billings Clinic

For Billings Clinic, the education and collaborative systems built during this clinical trial serve as a strong foundation for the planned implementation of commercial CAR T-cell therapy. While recognizing that the financial commitment to offering CAR T-cell therapy is significant, staff expressed that the efforts is worthwhile for patients. Offering commercial CAR T-cell therapy in a rural setting will reduce patient financial and psychosocial burden during treatment, ensure continuity of care, and support the Billings Clinic mission of offering the highest quality cancer care. The Director of Cancer Care, Rhonda Gradwell emphasized that the mission at Billings Clinic Cancer Center is to "treat people close to home with high quality, safe care" and providing innovative cancer treatments to patients who can be surrounded by their support network is the future of cancer care. ▲

References

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