Cellular Therapy Program at The Mount Sinai Hospital

Since 2018, The Mount Sinai Hospital has been an authorized treatment site for chimeric antigen receptor therapy, also known as CAR T-cell therapy. We have a robust commercial and investigational portfolio managed by a dedicated team with advanced expertise.

Our FACT-accredited service features a strong research program that is setting standards for safe and optimal patient care. We promote a shared care model that enables patients to come to us for CAR T-cell therapy while remaining under the care of their local physicians.

Directed by Keren Osman, MD—Associate Professor of Medicine (Hematology and Medical Oncology), bone marrow and stem cell transplant physician, and Director of Cellular Therapy—our care team includes physicians, nurses, pharmacists, cellular therapy lab and apheresis specialists, administrators, and quality monitors. Team members are highly trained and our hospital is specially equipped to ensure safe, cutting-edge care with CAR T-cell therapy; all ordering and dispensing physicians are CRS and neurotoxicity trained.

Mount Sinai was among the first institutions to participate in clinical trials using CAR T cells for multiple myeloma, including a trailblazing study with results reported in the *New England Journal of Medicine*. We continue to be a leader in CAR T-cell therapy for multiple myeloma, under the leadership of Deepu Madduri, MD, Associate Director of Cellular Therapy.

Our CAR T-cell therapy clinical trials can be found at https://oncore-search.mssm.edu/ (search for CAR T-cell and by disease).

We invite you to refer patients who may be eligible for clinical trials and products within our CAR T-cell therapy portfolio. Upon completion of treatment, your patient will return to your full care. We look forward to collaborating with you to provide treatment for your patients.

Contact information for referrals

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For Multiple Myeloma Clinical Trials

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Commercial CAR T-cell products available at The Mount Sinai Hospital

Yescarta® (axicabtagene ciloleucel)

YESCARTA® (axicabtagene ciloleucel) has been approved by the FDA for use in adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy.

	Requirements
Indications	Relapsed/Refractory Large B-Cell Lymphoma* -Diffuse Large B-Cell Lymphoma (DLBCL) not otherwise specified -Primary Mediastinal Large B-Cell Lymphoma -High Grade B-Cell Lymphoma -DLBCL arising from Follicular Lymphoma
Biomarker+	CD19
Lines of Therapy Required	Two or more
Treatment	Single infusion of CAR-transduced autologous T Cells intravenously

* Histologically proven

Yescarta® Package Insert: https://www.fda.gov/media/108377/download

Kymriah® (Tisagenlecleucel)

Kymriah® (Tisagenlecleucel) has been approved by the FDA for use in adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy.

	Requirements
Indications	B-cell precursor Acute Lymphoblastic Leukemia (ALL) -Refractory or in second or later relapse Relapsed/Refractory Large B-Cell Lymphoma* -Diffuse Large B-Cell Lymphoma (DLBCL) not otherwise specified -High Grade B-Cell Lymphoma -DLBCL arising from Follicular Lymphoma
Biomarker+	CD19
Lines of Therapy Required	Two or more
Treatment	Single infusion of CAR-transduced autologous T Cells intravenously

* Histologically proven

Kymriah® package insert: https://www.novartis.us/sites/www.novartis.us/files/kymriah.pdf

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Tecartus ® (brexcabtagene autoleucel)

	Requirements
Indications	Relapsed or refractory Mantle Cell Lymphoma*
Biomarker+	CD19
Lines of Therapy Required	Two or more
Treatment	Single infusion of CAR-transduced autologous T Cells intravenously

*histologically proven

Tecartus® Package Insert: https://www.fda.gov/media/140409/download

CAR T-CELL PROCESS

PRE-SCREENING

A CAR T-cell specialized provider conducts a complete medical history, performs a physical exam, reviews routine and specialized labs, and checks the condition of the heart and lungs. Imaging is done to determine the status and extent of the patient's disease. The patient meets with a CAR T-cell nurse coordinator who provides extensive education. The patient also meets with a CAR T-cell social worker who assesses psychosocial needs and a CAR T-cell pharmacist who identifies any medication adjustment or counseling needs. Once the clinical team determines the patient is eligible to receive CAR T-cell therapy, the patient is enrolled with the selected manufacturing company.

CELL COLLECTION AND MANUFACTURING

The clinical and administrative team coordinates cell collection once the patient's insurance is approved. About one week before cell collection, the patient is seen by the apheresis clinical team for pre-screening; this includes a thorough medical history review and specialized lab work. The patient returns about a week later for cell collection. The cells are immediately packaged and shipped by our cellular therapy lab to the manufacturing company for the genetic engineering and manufacturing process. This process can take up to 30 days. In some cases, pre-made "off the shelf" therapy products are ready for administration when needed (currently investigational only).

BRIDGING THERAPY

In some cases, patients may require bridging therapy to temporize the disease prior to CAR T-cell infusion. This is discussed in detail with the referring physician.

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INFUSION

Product infusion is done in the inpatient or outpatient setting depending on the patient's tumor burden, performance status, and risk factors. The infusion is generally administered through the patient's central line and can take up to 30 minutes. There are usually no immediate adverse events.

MONITORING AND FOLLOW UP

The patient is closely monitored for up to 14 days by the clinical team. Each product has varying expected onset of CRS neurotoxicity. Our clinical team members are experts in recognizing early symptoms and treating with conventional and novel therapies. The patient also undergoes real-time cytokine monitoring. Once discharged from daily care, the patient follows up with the CAR T-cell physician as frequently as needed or per clinical trial requirements. The patient is monitored for cytopenias, risk of infection, B-cell aplasia, CRS, neurotoxicity, performance status, and disease status. During this time, the team communicates clinical status updates to the referring physician. The patient is transferred to the referring physician once clinically stable and all relevant testing has been completed; this decision is made in partnership by the CAR T-cell physician and the referring physician. The patient returns as necessary to the CART-cell physician for long-term post-CAR T-cell monitoring.