An Overview of Transplant & Cellular Therapies

Methodist HOSPITAL

SARAH CANNON
Transplant & Cellular Therapy Program
at Methodist Hospital | San Antonio

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Dear Patient and Family,

Welcome to the **Sarah Cannon Transplant & Cellular Therapy Program at Methodist Hospital, San Antonio**. We are honored to have the opportunity to provide you with the transplant or cellular therapy that is best for you. The program was established in 1993 and has the distinction of being the first in North America to be accredited by the Foundation for the Accreditation on Cellular Therapy (FACT) for both adult and pediatric stem cell transplants as well as CAR T-Cell Therapy. Methodist Hospital, in partnership with Sarah Cannon Transplant & Cellular Therapy Network, is able to offer patients access to a number of quality, infrastructure, training and research resources, which we will discuss with you as we work to individualize your plan of care.

We have an exceptional multidisciplinary team that specializes in every aspect of the transplant process and will support you through every stage starting with the initial consult all the way to long-term survivorship. This educational handbook is one of the many valuable resources that you will have at your disposal to aid you in becoming knowledgeable about the transplant and cellular therapy process. This handbook will help you make decisions about whether a stem cell transplant or cellular therapy procedure is right for you.

As a transplant patient, you will be followed by a large interdisciplinary team consisting of expert medical staff, nurse coordinators, financial coordinators, staff nurses, social workers, rehabilitation staff, registered dietician and administrative personnel, all of whom will assist you in navigating this complex treatment. A key team member will be your nurse coordinator who will be your primary contact during your journey to transplant or cellular therapy treatment. Your nurse coordinator will work closely with your physician to manage your care.

Best Regards,
Your Transplant and Cellular Therapy Care Team

Methodist HOSPITAL

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Methodist Healthcare's adult and pediatric medical oncologists and hematologists are the leaders in blood cancer care for the south central Texas region. The program provides a multidisciplinary approach to cancer care, developing a personalized treatment plan for each patient and providing a dedicated nurse navigator who coordinates and monitors care for complex blood cancer patients.

The adult and pediatric Sarah Cannon Transplant & Cellular Therapy Programs at Methodist Hospital has performed nearly 4,000 transplants since the program's inception in 1993. It was the first in North America to be accredited by FACT and is FACT-accredited for both adult and pediatric-autologous and allogeneic stem cell transplants and CAR T-Cell Therapy. The program also provides patients with nationally-recognized care and access to the most innovative clinical trials.

Transplant Types: **Adult and Pediatric Autologous, Allogeneic - Related/Unrelated/Haploidentical/UCB, CAR T-Cell Therapy**
CAR T-Cell Therapy: **CAR T-Cell Therapy: FDA – approved therapies and clinical trials**

TRANSPLANT VOLUMES:

Adult & Pediatric	2019	2020	2021	2022
Totals	227	209	173	246

Physicians:

Adult Medical Team:
- Paul Shaughnessy, MD
- Carlos R. Bachier, MD
- Jose Carlos Cruz, MD
- Behyar Zoghi, MD, PhD

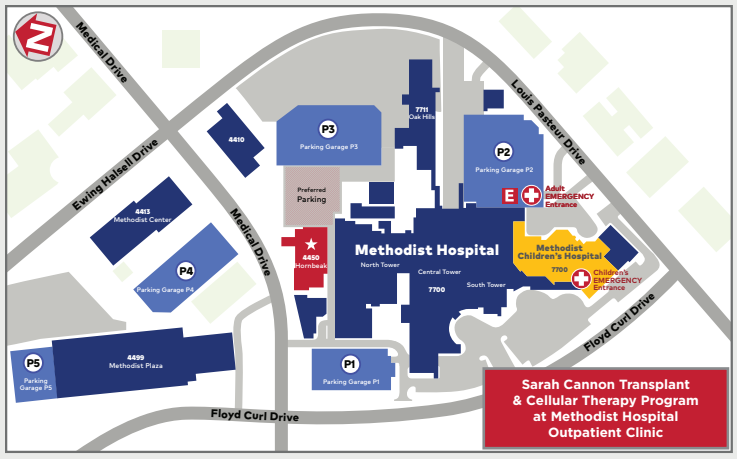
Pediatric Medical Team:
- Amanda Lipsitt, MD

Sarah Cannon Transplant & Cellular Therapy Program at Methodist Hospital
John Hornbeak Building,
4450 Medical Drive, 1st Floor,
San Antonio, TX 78229

Telephone:
(210) 575-3817

Telephone (For Patient Appointments and Referrals)
Adult Referrals:
(210) 575-9333
Pediatric Referrals:
(210) 575-2222

Directions/Parking:
Sarah Cannon Transplant & Cellular Therapy Program at Methodist Hospital is on the Methodist Hospital campus, located in the first floor of the John Hornbeak Building, 4450 Medical Drive, San Antonio TX, 78229. Surface lot parking, which is reserved for our patients, is available immediately adjacent the John Hornbeak building.



Website:
https://sahealth.com/specialties/bone-marrow-transplant

INTRODUCTION

What is Sarah Cannon?

Sarah Cannon is the Cancer institute of HCA Healthcare and brings cutting-edge cancer care to the communities in which we live and serve. This includes clinical trials and standard of care treatment options provided under the highest levels of quality. We set high expectations for how our blood cancer, transplant, & cellular therapy programs work to bring you the best care options provided by a compassionate and competent team.

Sarah Cannon Transplant & Cellular Therapy Network (SCTCTN) is made up of several cellular therapy programs throughout the United States. Our programs are recognized as leaders in patient care and outcomes and each program has clinical expertise in the field of complex blood cancers and cellular therapies. SCTCTN is one of the world's largest providers of cellular therapies, conducting more than **1,200** transplants a year and providing both clinical trial and FDA-approved cellular therapies.

Sarah Cannon Transplant & Cellular Therapy Network

CARE TEAM

Cellular Therapy: Your Multidisciplinary Care Team

Transplant & Cellular Therapies are complex therapies and require an experienced team of healthcare professionals to support you safely through this journey. We call these healthcare professionals your Cellular Therapy Multidisciplinary Care Team because they come from various specialties or "disciplines" to be part of your care team. This team will walk beside you throughout this care journey answering questions and providing knowledgeable support for you and your family/caregivers. The various members of this Multidisciplinary Care Team are on the following pages.

Transplant & Cellular Therapy Physician

On your first visit, you will meet with a cellular therapy physician who will manage and oversee your care. Cellular therapy physicians have extensive training in these therapies and will closely monitor all aspects of your care. Our physician team has multiple cellular therapy experts, and, it is likely that you will be seen by multiple cellular therapy physicians throughout your treatment process. Our care team will keep your primary oncologist informed of your treatment progress.

Other Specialty Physicians

Depending on your needs and side effects, the cellular therapy physician(s) may ask other specialty physicians to assist in your care. These specialty team members are part of the multidisciplinary care team and may include a pulmonologist (lung specialist), gastroenterologist (digestive specialist), nephrologist (kidney specialist), radiologist (radiological imaging specialist), and infectious disease specialist who will provide recommendations in collaboration with the cellular therapy physician(s). You may receive what feels like an overwhelming amount of information throughout the care journey, and your cellular therapy physician and/or nurse are always happy to answer any questions.

Advanced Practice Providers

Advanced Practice Providers (APPs) are nurse practitioners and physician assistants with advanced cellular therapy training and education. Together, with the cellular therapy physicians, the APPs help manage symptoms and overall care. They may also perform procedures such as bone marrow biopsies or lumbar punctures.

Transplant/Cellular Therapy Nurse Coordinator

The nurse coordinator will be your guide and central point of contact throughout the cellular therapy process. To ensure safety, the nurse coordinator will make certain that all of the necessary steps of the treatment plan ordered by your physician are completed. Education about the process will occur regularly with the nurse coordinator. They will review important information and serve as the resource for questions and concerns during treatment preparation. The coordinator also serves as a contact for caregivers.

Specialty Nurses

Additional specially trained nurses are part of the care team and may provide daily care, administer chemotherapy and stem cell infusions, provide symptom management, as well as provide patient and caregiver education. These expert nurses are a great source of information throughout your care journey.

Psychologists

Having an illness is emotionally stressful and you may need additional support, such as a psychologist, to assist in coping with stress, feelings of being out of control, as well as other valid emotions. As a member of the multidisciplinary care team, a psychologist is available to assist you and your family during the entire care journey.

Social Workers

One of the primary goals of the social work team is to provide information, resources, and assistance to you and your family. Assistance may include helping find information on financial resources, insurance coverage, coordination of transportation and housing, fertility planning (sperm and egg banking information), accessing community resources, and addressing any other concerns that may impact the patient, caregiver, or family.

Apheresis Team

The Apheresis team includes specially trained nurses who administer cell mobilization medications and manage the specialized machines used to collect stem cells and other cellular therapies. They are experienced and knowledgeable about how to manage care throughout the collection process. Medical technologists (MTs) may also be part of your Apheresis team as experts in cell collection.

Cellular Therapy Laboratory (CTL) Team

The CTL team is comprised of medical technologists (MTs) who are trained and experienced in the management of cellular products. They are responsible for ensuring cell products are safely processed and stored following collection. In addition, MTs prepare cell products for infusion.

Research Team

An important part of delivering cutting-edge therapies is offering access to clinical trials. Clinical trials help us find more effective ways to treat a particular disease. If appropriate, a research nurse or research coordinator may discuss a clinical trial which your cellular therapy physician has recommended.

Registered Dieticians

A registered dietician will review general nutrition and specific dietary needs. They will help provide guidance on food options when your appetite is decreased due to the chemotherapy side effects.

Financial Coordinators

Financial coordinators will assist you and your caregivers regarding financial responsibility and financial assistance, before treatment begins as well as for questions after treatment. They are responsible for communicating the treatment plan to your insurance provider and for obtaining financial clearance. These coordinators are experienced in this process and understand the information required by the insurance provider..

Chaplains

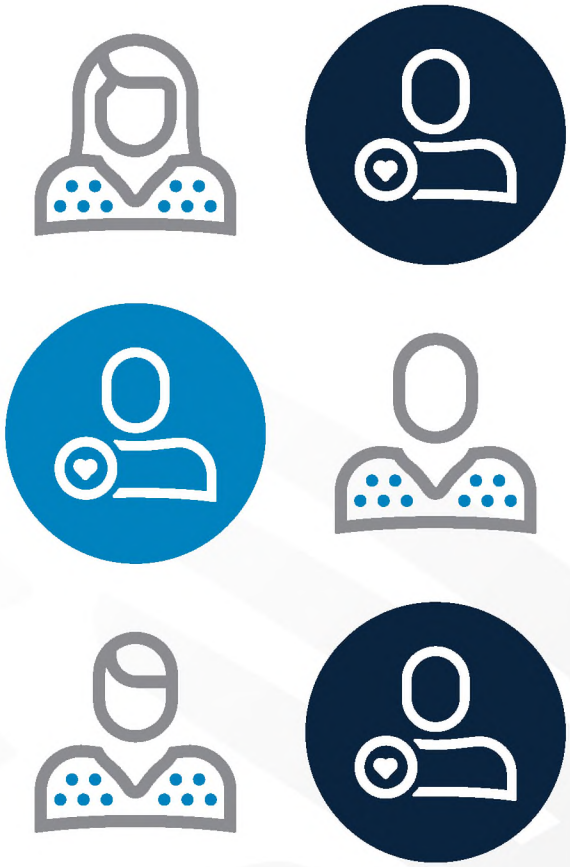
Chaplains are available to provide emotional and spiritual support to you, your caregivers, and family members throughout the treatment journey.

CELLULAR THERAPY

Cellular Therapy: An Overview for Patients and Caregivers

Overview

Cellular Therapy offers complex treatment options, and we have an expert team to walk beside you each step of the way, answering your questions and supporting your care decisions. Our care team will review your medical history to determine the best treatment options as there may be multiple cellular therapy options for your disease. The care team then works with you to design the best individualized treatment plan.



This manual is an introduction to the cellular therapies we offer across our network.

This manual is an introduction to the cellular therapies we offer across our network and will serve as a resource and guide book. Cellular therapy options include stem cell transplants, immune effector cell therapies (IECT), other immunotherapies, and gene modifying therapies.

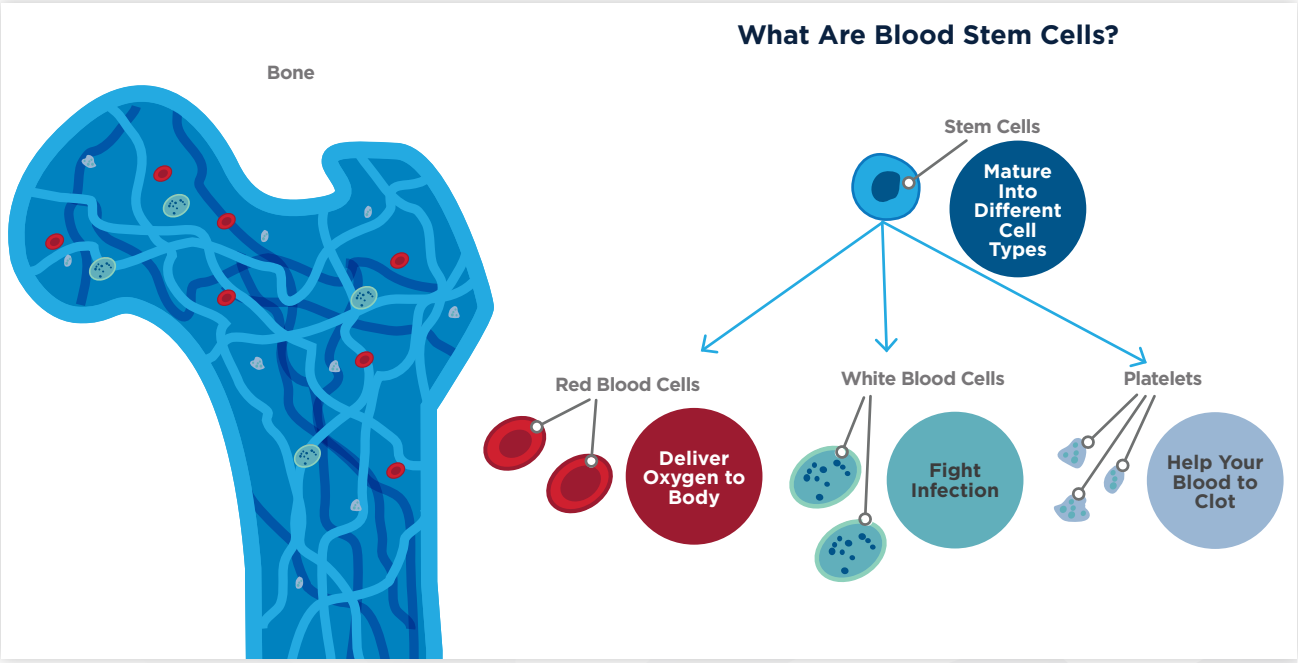
The terms used to describe these therapies can be confusing. Below are explanations of the terms used to describe different cellular therapies.

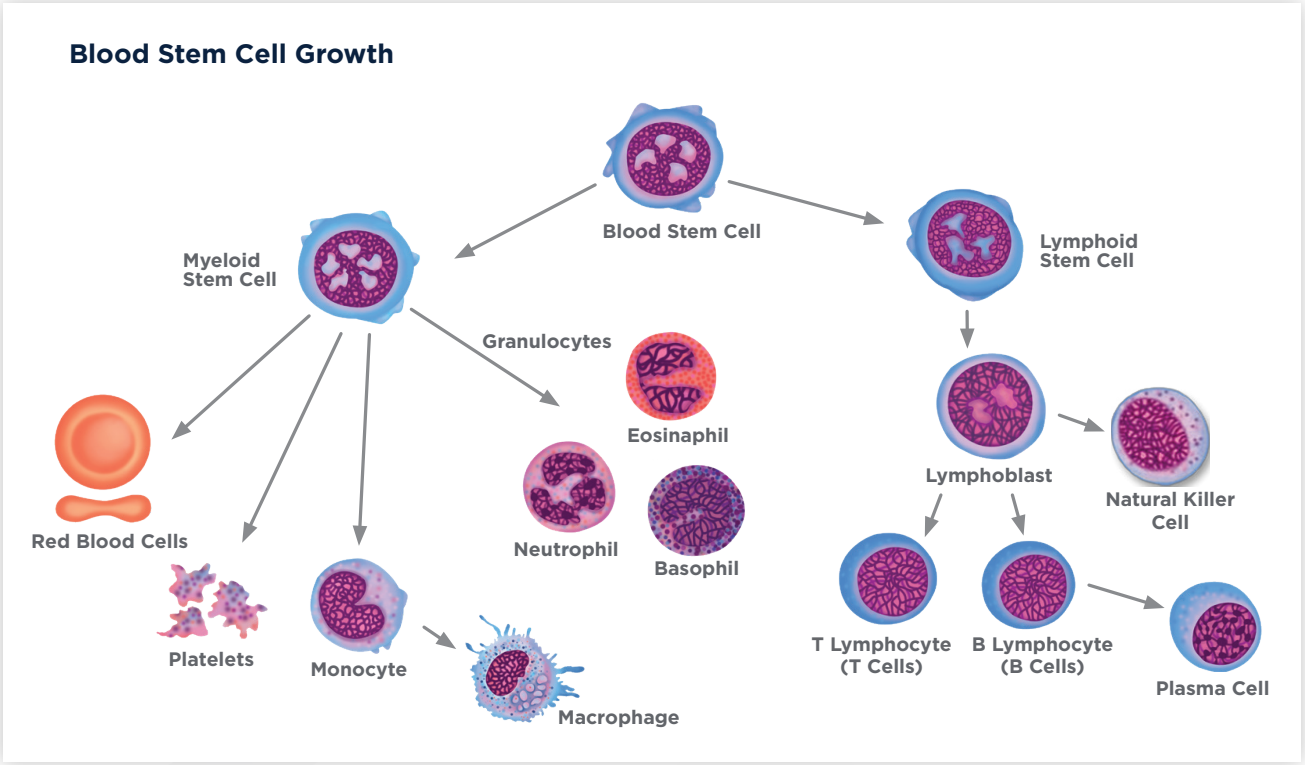
Type of Cellular Therapy	Description	Terms Used or Examples	Available as FDA-Approved Therapy or in Clinical Trials
Stem Cell Transplants	Therapy which uses blood stem cells to replace a patient's stem cells or to provide a new immune system to fight cancer cells	Bone Marrow Transplant (BMT) Blood & Marrow Transplant (BMT) Hematopoietic Cell Transplant (HCT) Hematopoietic Stem Cell Transplant (HSCT) Hematopoietic Progenitor Cell Therapy (HPC) Peripheral Blood Stem Cell Transplant (PBSCT) Stem Cell Transplant (SCT)	• FDA-approved therapy • Clinical Trials
Immune Effector Cell Therapies (IECT) or Adoptive Cell Therapies	Therapies which use engineered cells to improve the body's ability to identify and fight cancer cells	Chimeric Antigen Receptor T-cell Therapy (CAR T-cell Therapy)	• FDA-approved therapy • Clinical Trials
		Natural Killer (NK) Cell Therapy T cell Receptor (TCR) Therapy Tumor Infiltrating Lymphocyte (TIL) Therapy	• Clinical Trials
Gene-modifying Therapies	Therapies which modify a gene to reverse a disease process or reduce complications	CRISPR Therapies used to treat Sickle Cell Disease, Beta-thalassemia, hemophilia, cancer, and other diseases	• Clinical Trials

Stem Cell Transplants

Blood Stem Cells - What Are They?

Stem cells are special cells in the body used for repair and replacement of damaged or worn-out cells. There are several different types of stem cells in the human body including blood stem cells also known as hematopoietic stem cells. Blood stem cells are immature blood cells that develop into red blood cells (RBCs), white blood cells (WBCs), and platelets. These blood cells are essential to life. Blood stem cells are found in the bone marrow space in bones such as the hips, sternum, and skull. They are also found in small numbers in the blood that circulate throughout the body (peripheral blood).





Blood Stem Cell Growth

Bone marrow produces the stem cells that are the basic blood forming cells. In the graphic above, you can follow the blood stem cells as they mature into either myeloid or lymphoid stem cells. Myeloid stem cells further develop into neutrophils, eosinophils, and monocytes (types of WBCs), as well as RBCs and platelets. Lymphoid stem cells develop into other types of WBCs known as T-cells or B-cells. These cells are important for the body's immune system and its ability to recognize foreign cells such as bacteria.

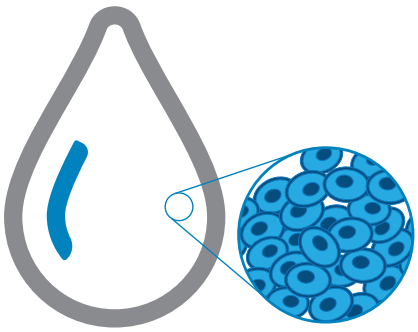
What is a Stem Cell Transplant?

A stem cell transplant is an infusion of healthy stem cells. These healthy stem cells reproduce into normal red blood cells, white blood cells, platelets, and other blood cells.

One purpose of a stem cell transplant may be to assist in the recovery of bone marrow function as a result of high-doses of chemotherapy and/or radiation. Stem cell transplant can also be used to stimulate the immune system to fight cancer.

All patients prior to receiving a stem cell transplant will receive chemotherapy with or without total body irradiation (TBI). This is referred to as the conditioning regimen or preparative regimen.

There are two types of stem cell transplants: **autologous** and **allogeneic**. Your care team will recommend the best option to treat your disease.



Healthy stem cells reproduce into normal red blood cells, white blood cells, platelets, and other blood cells.

Autologous Transplants

An autologous transplant uses your own stem cells. The treatment process, which includes evaluation, pre-transplant workup, apheresis, stem cell transplant, and recovery, will extend over approximately four months.

Evaluation: Assessment by a cellular therapy physician of whether you are a potential candidate for autologous transplant.

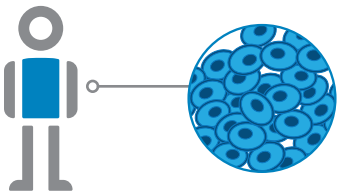
Pre-transplant Work-up: Testing performed to show if your organs and overall health meet the requirements to safely receive an autologous transplant.

Apheresis: In preparation for the transplant, stem cells are collected from the patient using a special machine that circulates your blood and pulls out the cells needed for the transplant. These cells are carefully frozen and stored in a cellular therapy laboratory until needed.

Stem Cell Transplant: Chemotherapy is administered in much higher doses than with standard chemotherapy regimens. These high doses of chemotherapy, called the conditioning regimen, target diseased cells and also affect normal blood cells. Therefore, without a stem cell transplant, you would not recover normal bone marrow function. In order to treat the disease and allow recovery of the bone marrow, the pre-collected stem cells are re-infused after completing the conditioning regimen. The re-infusion is referred to as a “stem cell transplant” or sometimes called a “stem cell rescue”.

Recovery: Approximately 10-12 days following the transplant, the new stem cells will begin to grow in your bone marrow space and produce healthy white blood cells, red blood cells, and platelets.

An **autologous** transplant uses a patient’s own stem cells.



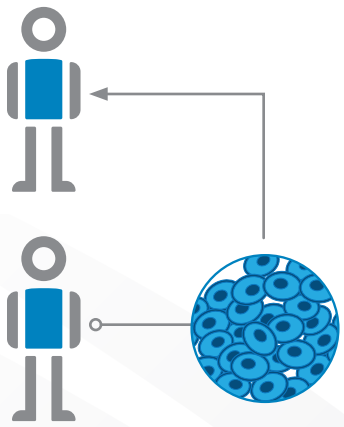
Allogeneic Transplants

Allogeneic transplants use stem cells from a donor. A donor can be a family member, an unrelated person, or from umbilical cord blood. It can take a minimum of one month or longer to identify a donor and begin the transplant process.

There are three types of allogeneic transplant conditioning regimens that include chemotherapy with or without total body irradiation (TBI): myeloablative, reduced intensity, and non-myeloablative (see below). These conditioning regimens have multiple purposes.

- First, they target diseased cells and destroy them.
- They also suppress the immune system to prevent rejection of the donor cells.
- The donor cells may also help to fight against diseased cells by creating a graft versus tumor effect (GVT). The graft cells (donor cells) react against diseased cells (tumor cells) to kill them.

An allogeneic transplant uses stem cells from a donor.



All allogeneic transplants require medications to suppress your immune system. Following this type of transplant, patients will need medical care and medications to manage symptoms for an extended period of time.

Conditioning Regimens for Allogeneic Transplant:

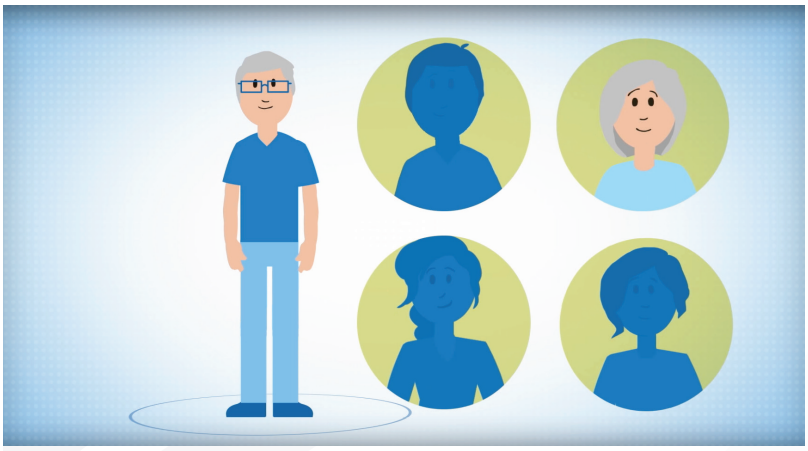
- **Myeloablative regimens** - Also known as “ablative” or ”high intensity” therapy. This type of transplant uses chemotherapy in higher doses than standard chemotherapy regimens and may also be used in combination with radiation. These regimens primarily rely on the conditioning regimen to destroy your disease.

- **Reduced intensity regimens**- This type of transplant uses moderate doses of chemotherapy with or without radiation. It is often used for patients who cannot tolerate high intensity therapy.

- **Non-Myeloablative regimens** - Also known as a 'low intensity' therapy. This type of transplant uses low doses of chemotherapy with or without radiation, and relies on the graft versus tumor effect as the primary means to destroy diseased cells. It is often given to patients who cannot tolerate high intensity therapy and/or for certain disease types.

Finding a Donor

The first step in planning for an allogeneic transplant is to find a suitable donor. This is done through the process of Human Leukocyte Antigen (HLA) typing. HLA typing is a molecular laboratory test that looks at cell markers using a blood sample or cheek swab.



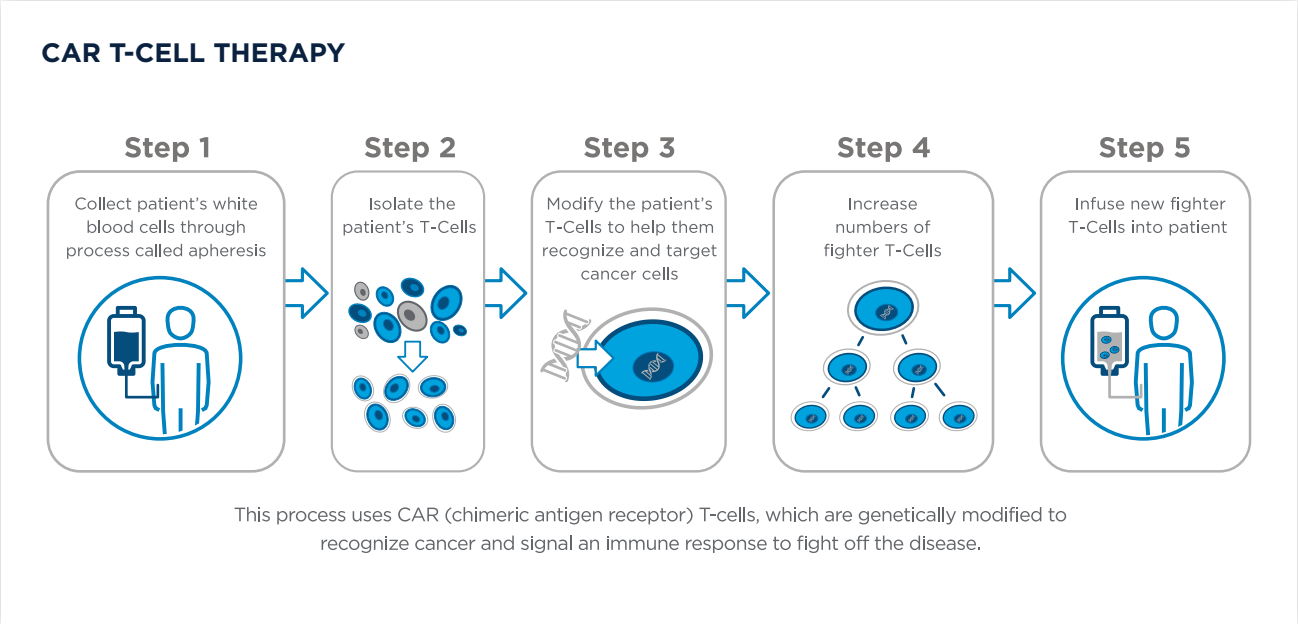
Siblings who share the same mother and father have the best chance of matching.

People receive half of their DNA from their mother and half from their father. Siblings that share the same mother and father have the best chance of matching. There is a one in four, or a 25% chance, that any one of a person's siblings will be a match, and a 50% chance to have a sibling as a half match or haploidentical donor. If there is no sibling match or half match, or if there are no siblings, there are unrelated donor registries that may have potential HLA matched donors. The care team may also request testing of parents or children, if indicated. The transplant nurse coordinator and the donor coordinator will arrange for the testing.

Immune Effector Cell Therapy

What is Immune Effector Cell Therapy?

There are several types of Immune Effector Cell Therapy (IECT). The purpose of immune effector cell therapy is to modify the body's immune system to improve its ability to fight cancer. The most commonly used IECT is Chimeric Antigen Receptor (CAR) T-cell Therapy. In autologous CAR T-cell therapy, a patient's T-cells are collected and reprogrammed to find and destroy cancer cells. Allogeneic CAR T-cell Therapy uses a donor's T cells to destroy cancer cells.



Autologous CAR T-cell Therapy is available as both an approved therapy and in clinical trials to treat several blood cancers. This therapy uses your T cells which are collected and sent to a laboratory to be reprogrammed to find and destroy cancer. Prior to receiving the CAR T-cells, you will receive chemotherapy. After the cells are infused, you will be monitored closely for several weeks for side effects related to the therapy.

Allogeneic CAR T-cell Therapy is available in clinical trials. Healthy donors provide the T cells which are then programmed to fight specific types of cancer. These are called "off-the-shelf" CAR T-cells because you do not have to wait for your cells to be manufactured in a laboratory. You will receive chemotherapy prior to receiving the allogeneic CAR T-cells and be monitored closely for side effects for several weeks.

There may be other types of IECT treatment options available in clinical trials. Speak with your physician if you have interest in exploring these options.

Other Therapies

Natural killer (NK) cell therapy, T-cell receptor (TCR) therapy, and tumor-infiltrating lymphocyte (TIL) therapy are other examples of cellular therapies available as treatment options under clinical trials for specific diseases. If there are clinical trials available for your disease process and status, the care team will discuss these options with you and your family.

Gene-Modifying Therapy

What is Gene-Modifying Therapy?

Gene-modifying therapy is used to correct deficiencies or diseases by editing defective chromosomes and then returning the edited cells back to the patient.

Currently available through clinical trials, gene-modifying therapies include treatments for sickle cell disease, beta-thalassemia, genetic conditions, and some cancers.

CELLULAR THERAPY REQUIREMENTS

Cellular Therapy Requirements

Caregivers

This treatment is not possible without the support of caregivers. There are certain phases of the process where a caregiver needs to be with you 24 hours per day, seven days per week. The time commitment for a caregiver can range from 30 days (autologous transplant and immune effector cell therapy) up to 100 days or longer (allogeneic transplants).

Caregiver duties may include:

- ❑ Assisting with medications
- ❑ Providing care for the central venous catheter
- ❑ Transportation
- ❑ Cooking
- ❑ Cleaning
- ❑ Grocery shopping
- ❑ Picking up prescriptions
- ❑ Handling emergencies

Prior to finalizing the treatment plan, patients will need to identify a reliable caregiver(s) for treatment support. Sometimes it is one individual, but often several people share in the responsibility of providing 24-hour care. The nurse coordinator will discuss specific caregiver requirements.

It is a *program requirement* that patients and caregivers attend this class or the in-person meeting.

Education

It is important that you and your caregivers are knowledgeable, informed, and involved in the entire treatment plan.

Each of our programs has either a patient/caregiver class or an in-person meeting designed to prepare patients and caregivers for the process. Clinical experts from the care team will provide education both verbally and in written form and will assist in preparing patients and caregivers for the entire process.

It is a program requirement that patients and caregivers attend this class or the in-person meeting. The nurse coordinator will provide an educational plan. Once a patient decides to move forward with cellular therapy treatment, a Patient and Caregiver Education Manual will be provided that outlines what to expect and how to proceed safely through the process.

During visits with the cellular therapy physician or APP, patients are encouraged to ask questions and obtain information about their individualized treatment plan and the cellular therapy process.

Smoking/Vaping/Marijuana/Alcohol Use

The use of tobacco products, marijuana, illicit drugs, and alcohol are not permitted during the cellular therapy treatment process. This is due to potential serious complications related to cellular therapies that can occur when using these substances. In order to minimize the risk of infectious complications and organ dysfunction, these will not be permitted. We understand patients may need support to stop using these products and encourage a discussion with the care team to develop a support plan.

Driving

Driving will be restricted during the treatment process. Restrictions depend on the treatment plan and medical condition. These restrictions can range from a few weeks to a few months.

Dental Evaluation

An examination by a dentist is a requirement to ensure there are no problems with the patient's teeth or mouth that could cause infections or other issues during the treatment process. This is necessary even with dentures. Please check with the transplant/ cellular therapy nurse coordinator regarding this requirement.

It is recommended that patients receive a dental evaluation as soon as possible so that any procedures recommended by the dentist can be completed prior to treatment. For safety, patients should check with their primary Oncologist or cellular therapy physician before having any dental procedures performed.

This process can be emotionally stressful; therefore, patients are *required* to meet with a member of the psychosocial team.

Meeting with the Psychosocial Team

The cellular therapy treatment process can be emotionally stressful; therefore, you will be required to meet with a member of the psychosocial team. This team includes psychologists and social workers who are experienced in supporting patients and caregivers through the cellular therapy journey. This process affects everyone who is a part of your support system; therefore, we encourage the primary support system to attend the appointment. It is important for the care team to know how to not only support you, but also your family.

Advance Directives will be discussed during this meeting. When a person provides verbal or written instructions on their wishes regarding future healthcare decisions, it is called an Advance Directive. You have the right to make your own healthcare decisions. As healthcare providers, we honor patients' wishes regarding these decisions. Thus, we strongly encourage patients to fill out an Advance Directive. These directives can help guide the healthcare team and your family should there be a time during the process when you are too sick to think or communicate clearly. We ask that you provide a copy of the Advance Directive to be included in your medical record.

The two main types of Advance Directives patients should consider completing include: 1) a living will; 2) a medical durable power of attorney. A **living will** is a document that expresses wishes and desires regarding artificial life support if a person is facing end of life decisions. A **medical durable power of attorney** appoints someone (for example, a family member, significant other, or friend) trusted to express a patient's healthcare wishes if they are unable to do so for themselves. A member of the psychosocial team will discuss these options and address any concerns.

FINANCIAL INFORMATION

Financial Information & Considerations

Leave of Absence from Work

This type of treatment will require a leave of absence from work. A minimum expectation for an autologous transplant and immune effector cell therapy is six to twelve weeks. The time away from work when receiving an allogeneic transplant can range from three months to a year or more. The cellular therapy physician and nurse coordinator will discuss time off work with you.

You and/or your spouse will need to contact your employer's Human Resources Department to ensure continuation of employee benefits and to obtain information regarding medical leave and disability. This information can be difficult to understand. A social worker or your nurse coordinator can walk you through the options your employer offers.

Disability and Family Medical Leave Act (FMLA) Forms

The care team can assist with disability and FMLA forms. The paperwork should be completed within ten business days of you providing it to the care team.

Insurance

Insurance is a contract between the patient, his or her employer (if employer-based), and the insurance company. It is important for you to read your plan's benefits, rules, and regulations. The cellular therapy program provides access to a financial coordinator and a social worker to assist as needed, but it is your responsibility to understand your insurance policy.

Be sure to inform the financial coordinator of all health insurance policies in which you are enrolled before, during, and after treatment. It is also critical to notify them of any changes in coverage. Changes in insurance may change treatment coverage.

Planning for Cellular Therapy Treatment Options:

- There are two types of insurance plans—commercial and government plans. Examples of commercial insurance plans, also known as managed care plans, include United Healthcare, Cigna, Aetna, Blue Cross Blue Shield, and many others. A government plan includes Medicare, Medicaid, TriCare, etc. Additionally, some government plans offer managed plans, for example Medicare Advantage or supplemental plans through commercial insurance providers. Finally, a plan may access another network for transplant care, such as Optum or LifeSOURCE. The financial coordinator can answer questions about these different types of plans. Patients covered through plans that require a referral from primary care physicians to specialists are responsible for following their insurance carriers rules.

Patients covered under managed care plans (HMO/PPO/EPO) are responsible for following their insurance company rules regarding referrals from primary care physicians to specialists.

The patient is responsible for deductibles and co-insurances.

- Failure to comply with the insurance company's requirements will make it necessary for the program to bill you directly for charges incurred during a non-referred, non-covered visit.
- The program will file and process claims for insurance companies with whom they have contracts. Otherwise, payment is expected at time of service. Upon request, a copy of the bill will be furnished to you for insurance claim filing through the billing department.
- Co-payments are required to be paid at the time of service. Co-payments can be expected for each office visit, treatment, and often times lab services, as required by the insurance plan.
- You are responsible for deductibles and co-insurances.
- Any services or procedures not covered by the insurance company are your responsibility.
- If at any time you or your spouse elect to enroll in COBRA coverage or are considering changing insurance providers, please contact the financial coordinator prior to selection. They may provide you with valuable information regarding your options.

Obtaining Insurance Approval for Cellular Therapy

A financial coordinator will obtain information about your insurance coverage and benefits. You may also be assigned a case manager by the insurance provider. This person will be a good resource.

Even while deciding whether you want to proceed with the recommended treatment plan, it is a good idea to determine what insurance coverage is available for the procedure. Approval for payment by your insurance company does not mean you are required to proceed with treatment. This initial review of benefits is not the same as "preauthorization" or final approval by the insurance company. Almost all insurance companies require a detailed review of the case by an insurance physician prior to actual approval for cellular therapy and related services.

Preauthorization

Preauthorization by the insurance company means the company agrees that treatment is appropriate and medically necessary. However, payment for the treatment is still based on the individual policy. You may be responsible for part of the payment or for related services. The program's goal is to limit your out-of-pocket expenses as much as possible and to keep you informed about the interactions with your insurance company. Personalized financial counseling is available for patients.

Out-of-Pocket Expenses

Insurance companies often limit the money they allocate for specific services. This means that some things, such as housing, dental exams, and outpatient prescriptions may not be covered. The program will do their best to let you know as soon as possible about any restrictions. However, it is your responsibility to understand your insurance policy. The best way to get information regarding the policy is through your employer's benefits/human resources personnel or by calling the insurance company's customer service line.

Some specialty drugs require prior authorization by the insurance company. The dedicated transplant pharmacists are very familiar with this process and will work very closely with your insurance, if this occurs.

Other Financial Resources

The social worker is available to help with determining the potential eligibility for assistance programs and can help in filling out the necessary forms. Assistance programs include social security disability and supplemental security income. You may also have disability coverage through your employer. There are some limited community resources that may be available. Please contact the social worker for specific information or eligibility requirements.

Fundraising/Grants

To help with out of pocket costs that are not covered by insurance, fundraising might be an option. However, check with the financial coordinator to see if fundraising may interfere with insurance coverage before beginning. You may also be eligible for grants to help with these expenses. The Leukemia & Lymphoma Society, American Cancer Society, and the National Marrow Donor Program are examples of organizations that may be able to assist you. A social worker is available to discuss these options.

Housing

The nurse coordinator and social worker will discuss local housing needs. If the patient's home and its location do not meet program requirements, alternate local housing during certain phases of the process may be required. The cost of this housing may be covered by insurance. However, if it is not, this will be the patient's financial responsibility. If needed, a social worker can assist in finding lodging.

Our team, alongside the Sarah Cannon Transplant & Cellular Therapy Network, looks forward to providing exceptional care and supporting you and your family throughout the cellular therapy journey.

COMMONLY USED TERMS AND ABBREVIATIONS

Commonly Used Terms and Abbreviations

Allogeneic (Allo) Transplant: a stem cell transplant from one person to another. Stem cell donors may be related or unrelated.

ANC (Absolute Neutrophil Count): calculation of the number of neutrophils in the bloodstream which are available to fight infection. The ANC is a measure of how vulnerable a patient is to infection.

Anemia: a lower than normal number of red blood cells circulating in the blood.

Apheresis: a procedure that circulates blood through a machine to collect specific cell components, for example, stem cells or platelets.

Autologous (Auto) Transplant: a stem cell transplant where a patient's cells are collected, frozen, and then returned to the patient.

Blood Stem Cell: a cell from which all other blood cells originate; also called a pluripotent stem cell.

Cellular Therapy: the infusion of human cells to replace or repair damaged tissue and/or cells. Many different types of cells may be used as part of the therapy or treatment for a variety of diseases and conditions.

Central Venous Catheter (CVC): a thin flexible tube (catheter) that is surgically placed in a large vein in the upper chest or neck. Examples of these types of catheters are Opti Flows, Hickmans, Quintons, Groshongs, and Trifusions. Fluids, such as blood and/or chemotherapy, may be infused through this catheter and blood samples can be drawn from it. Stem cells may also be collected and infused through it.

Chemotherapy: medications used to treat cancer or other diseases by destroying abnormal cells or slowing their growth.

Conditioning Regimen: chemotherapy, radiation and/or immunosuppressive agents given in preparation for stem cell transplant. Also known as the preparative regimen.

Complex Blood Cancers: diseases of the blood and blood forming tissues.

Gene Editing: the ability to change an organism's DNA by adding, removing, or altering specific sections in the gene.

Graft Versus Tumor (GVT): an effect where transplanted cells from the donor attack the patient's diseased cells.

Haploidentical Transplant: an allogeneic stem cell transplant that uses stem cells from a sibling, parent, or child. Haploidentical matches are also called "half-matches."

Illicit Drugs: Highly addictive and illegal substances such as heroin, cocaine, and methamphetamines.

Lymphocyte: One of the main types of white blood cells that help protect the body from illness.

Myeloablative Transplant: a stem cell transplant using high-dose chemotherapy in doses higher than standard chemotherapy, with or without radiation, to destroy diseased cells and suppress the immune system.

Natural Killer (NK) Cells: a type of white blood cell called a lymphocyte which may be used to fight cancer cells.

Neutropenia: a low number or lack of neutrophils, the white blood cells needed to fight infection.

Non-myeloablative transplant: an allogeneic stem cell transplant that uses low doses of chemotherapy and radiation and relies heavily on the graft vs tumor effect.

Peripherally Inserted Central Catheter (PICC): a thin, flexible tube (catheter) that is usually inserted into a vein in the upper arm. PICCs are designed to stay in place for weeks or even months and provide access for IV fluids, blood products, chemotherapy, and other medications. Blood samples can also be drawn through a PICC.

Platelet (PLT): a type of blood cell that helps the blood to clot. The normal range for platelets is between 150,000-400,000/mm^3. An increased risk of serious bleeding occurs when platelets drop below 50,000/mm^3.

Red Blood Cell (RBC): a type of blood cell containing hemoglobin that transports oxygen throughout the body.

Total Body Irradiation (TBI): a type of radiation delivered to the entire body.

Tumor Infiltrating Lymphocyte (TIL) Therapy: process of using patients' own cells, which are manipulated and re-infused into the patient to infiltrate the tumor and destroy the tumor cells.

Unrelated Donor (URD Transplant): an allogeneic transplant where the donor and recipient are not related.

White Blood Cell (WBC): the cells that help your body to fight infections. Normal ranges for white blood cells are between 4,500-11,000/mm3. Different types of white blood cells include neutrophils, lymphocytes, monocytes and eosinophils.

*Glossary Sources:

- **Sarah Cannon Transplant & Cellular Therapy Network leadership**
- National Comprehensive Cancer Network
- National Marrow Donor Program (NMDP)
- Cancer.net
- The American Association of Blood Banks

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