



Patient and Caregiver Education Booklet

 **mozobil**[®]
(plerixafor) injection

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Introduction

This booklet is designed to provide you with information regarding autologous stem cell transplant and the use of Mozobil® (plerixafor) injection to help mobilize stem cells.

Mozobil is approved by the United States Food and Drug Administration (FDA) to be used in combination with another agent (granulocyte-colony stimulating factor [G-CSF]) to mobilize hematopoietic stem cells into the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM). Mozobil is not intended for hematopoietic stem cell transplantation mobilization and collection in patients with leukemia.

Throughout this booklet, you will find words highlighted in **green**; these are commonly used terms by your transplant team. Definitions of the terms are located in the glossary section.

This booklet also contains a sample mobilization calendar for you to clearly see the timing of all the steps involved. A blank calendar is provided for you to record your personal mobilization schedule after talking to your transplant physician.

At the end of this brochure, you will find a section to record any questions you may have for your transplant physician as well a section listing some other useful resources.

The information in this booklet can serve as a helpful tool throughout the course of your transplant. However, it is not intended to replace the information provided by your physician and transplant team nor is it a substitute for the discussions you should have with your transplant team.

Always consult your physician and transplant team if you have any questions or concerns regarding your treatment.

Please see additional Important Safety Information in this piece and click [here](#) for full Prescribing Information.

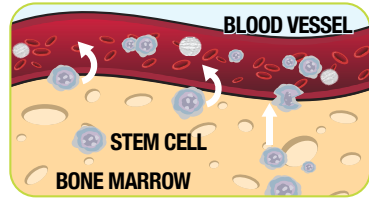
The Stem Cell Transplant Process

These pictures describe the transplant process in general. Your transplant process will be individualized by your center.

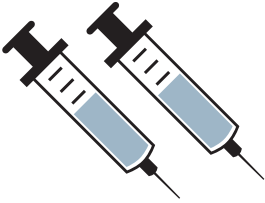
Step 1: Pre-transplant Evaluation



Step 2: Stem Cell Mobilization



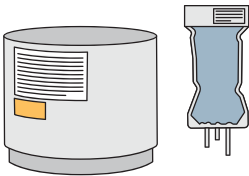
Step 2a: Injections for Mobilization



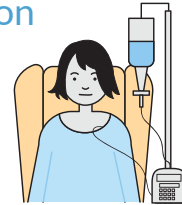
Step 3: Stem Cell Collection



Step 4: Stem Cell Freezing and Storage



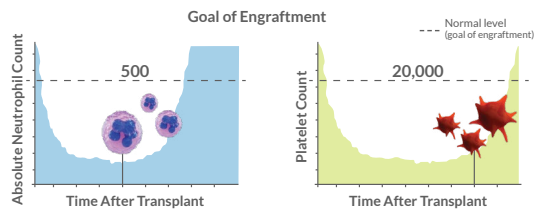
Step 5: Pre-transplant Chemotherapy and/or Radiation



Step 6: Stem Cell Transplant



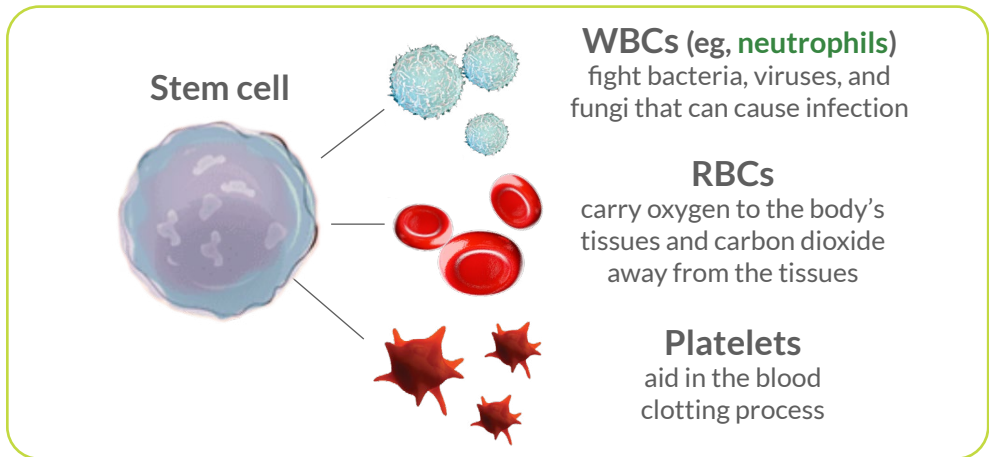
Step 7: Engraftment and Recovery



Chapter 1: The Stem Cell Transplant

What are stem cells?

Hematopoietic stem cells (referred to in this booklet as *stem cells*) are unique cells that are primarily located in the **bone marrow** and mature into a number of blood cell types found in your body. The blood cells that are most important for stem cell transplantation are **white blood cells (WBCs)**, **red blood cells (RBCs)**, and **platelets**.



Where are stem cells found?

In adults, most stem cells can be found in the bone marrow. Stem cells that leave the bone marrow and circulate into the bloodstream are called peripheral blood stem cells (PBSCs).

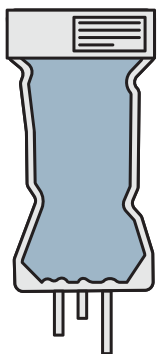
Did you know?

Although very few PBSCs are found outside the bone marrow in the bloodstream, their numbers can be increased by providing certain drug treatments, known as **mobilization** agents.

What is autologous stem cell transplant?

Autologous stem cell transplant (referred to as *stem cell transplant* throughout the rest of this booklet) is one type of **hematopoietic stem cell transplant**, where your own previously collected stem cells are reinfused back into your body through your bloodstream like a blood transfusion. The stem cells then travel through the blood to the bone marrow, where they make their home. These cells then grow and divide to produce mature WBCs, RBCs, and platelets.

Why is stem cell transplant performed?



Stem cell transplant is used commonly to treat forms of blood cancer, most commonly **non-Hodgkin's lymphoma (NHL)** and **multiple myeloma (MM)**. A stem cell transplant allows a patient to receive high-dose chemotherapy and/or radiation to kill the rapidly dividing cancer cells and to make room for new, healthy cells.

Although these anticancer treatments are among the most effective available, they do not have a specific target and can destroy rapidly dividing normal cells as well. A stem cell transplant enables a patient to produce new blood cells to replace those destroyed during treatment by the **reinfusion** of your own stem cells that were previously collected, frozen, and stored.

What is stem cell mobilization and collection?

To be able to proceed to stem cell transplant, you must have enough stem cells collected. These stem cells are collected before you receive high doses of chemotherapy and/or radiation. The cells are then preserved, frozen, and stored until the time of transplant.

What is the stem cell transplant process?

Step 1: Pre-transplant Evaluation



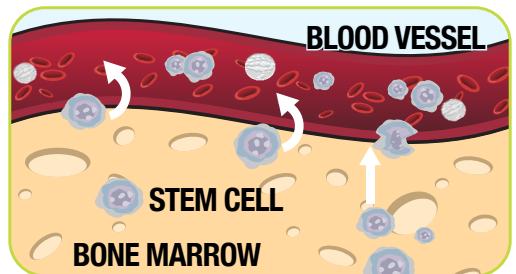
Once you are referred to the transplant center, you will have multiple pre-transplant tests done to ensure you are a good candidate for transplant.

These tests include evaluations of your lungs, kidneys, liver, and heart, along with nutritional evaluations and infection screenings.

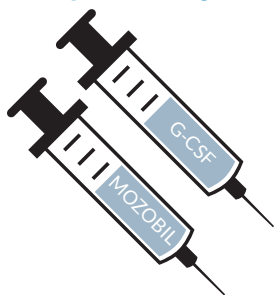
The results of these tests are key to determining your eligibility for stem cell transplant.

Step 2: Stem Cell Mobilization

This is a process whereby stem cells are stimulated to move out of the bone marrow space into the bloodstream. There are 3 main methods of mobilization that will be discussed in more detail in Chapters 2 and 3.



Step 2a: Injections for Mobilization



Under normal circumstances, stem cells make up only a small portion of the cells found in the peripheral blood. However, the number of PBSCs can be increased by administering medications such as growth factors (including G-CSF [filgrastim and filgrastim-sndz]), chemotherapy,* and agents such as Mozobil® (plerixafor) injection.

Indication

Mozobil is indicated in combination with G-CSF to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with NHL or MM.

*Chemotherapy is not FDA approved for the mobilization of stem cells.

Step 3: Stem Cell Collection

Apheresis is the process by which stem cells are separated from other components of the blood and collected for reinfusion at a later date.

In the past, stem cells were collected from the bone marrow, however, today it is possible to collect stem cells from the peripheral blood.

Collecting Stem Cells From Peripheral Blood

During PBSC collection, you will be connected to an apheresis machine, also known as a cell separator. Blood will leave your body through a **central venous catheter (CVC)**. The machine will collect the stem cells, and then, the remaining blood components will be returned to your body through the catheter. A blood thinner called citrate may be slowly added to your blood during this process to help prevent blood clotting.



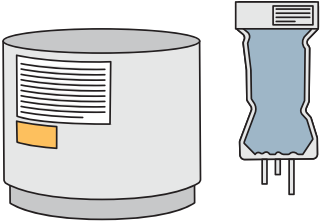
The collection of stem cells from your peripheral blood may take about 4 to 6 hours to complete each day. Repeated, daily collections may be needed to accumulate enough stem cells for your transplant.

Important Safety Information

- Severe, life-threatening allergic reactions (anaphylaxis) can happen in people who take Mozobil. Tell your doctor right away if you experience hives (itchy raised bumps), eye swelling, or trouble breathing.

Please see additional **Important Safety Information** in this piece and click [here](#) for full Prescribing Information.

Step 4: Stem Cell Freezing and Storage



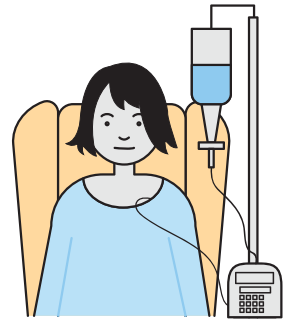
After each apheresis session, your stem cells will be processed and frozen using a technique known as **cryopreservation**. A chemical called **dimethylsulfoxide (DMSO)** is mixed with the stem cells to protect them during freezing. Your frozen stem cells will be ready and waiting for you once you have completed your high-dose chemotherapy and/or radiation.

Did you know?

Your stem cells can be frozen and stored for many years.

Step 5: Pre-transplant Chemotherapy and/or Radiation

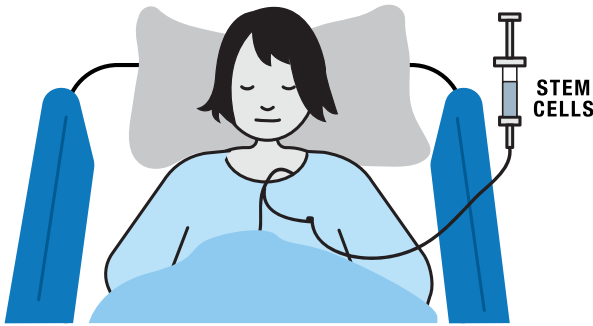
After the stem cells are collected, or at a later date, you will receive high-dose chemotherapy and/or radiation therapy, called the **conditioning or preparative regimen**. These higher doses of chemotherapy and radiation are intended to kill any remaining cancer cells and make room for your new cells to grow.



If you experience side effects, they may be similar to those you experienced with previous treatments, but they could also differ in severity. Talk to your transplant physician about what you might expect.

Step 6: Stem Cell Transplant

Once the chemotherapy drugs have been cleared from your body, you are ready for your stem cells. On the day of your stem cell transplant, your previously collected stem cells will be brought to your bedside, thawed, and reinfused into your bloodstream through your CVC. Infusion times range from 1 to 5 hours, depending on the volume of cells to be reinfused.



During and for a period after the reinfusion, you will be checked frequently for signs of fever, chills, hives, a fall in blood pressure, and/or shortness of breath, among other potential side effects. These side effects are rare and usually mild. In addition, following chemotherapy you may experience other common side effects such as fatigue/tiredness, nausea, vomiting, diarrhea, mouth sores, and hair loss. Talk to your physician and transplant team about any side effects you might be concerned about.

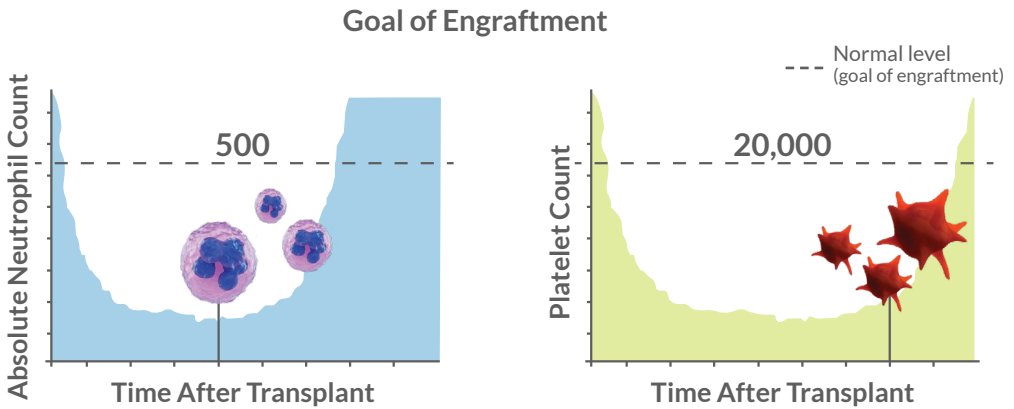
Did you know?

After you receive your stem cell transplant, you may notice a distinct, garlic-like taste in your mouth, and your body may smell like garlic, but these normal side effects should fade away after a few days. The odor is from the DMSO that was used to preserve your cells.

Step 7: Engraftment and Recovery

As soon as your stored stem cells are reinfused, they travel through your bloodstream into the bone marrow space. Even though the stem cells start moving towards the bone marrow right away, it will be close to 10 to 20 days before these reinfused cells are able to mature and produce healthy new blood cells, a process called **engraftment**.

One of the first signs of engraftment is increased **absolute neutrophil count**. Both neutrophil recovery and platelet recovery are important for engraftment.



Until engraftment occurs, you may be at risk of developing an infection, and experience fatigue/tiredness, anemia (low red blood cell count), bruising, and/or bleeding. Your physician and transplant team will watch you very closely during this time.

During the entire transplant process, it is important to maintain your nutrition, physical activity, and overall health. Talk to members of your transplant team to determine an appropriate diet and level of activity for you.

Chapter 2: Stem Cell Mobilization

Why is stem cell mobilization important?

Stem cell mobilization is a process in which stem cells are moved out of the bone marrow space into the bloodstream so that they are available for collection for future reinfusion. The cells are then preserved, frozen, and stored until the time of transplant.

Mobilization is a key step in ensuring that you have enough stem cells in the bloodstream for collection, enabling you to proceed to transplant.

What is characterized as a successful mobilization?

Some preferred characteristics of a mobilization regimen include:



Mobilizing enough stem cells for transplant

- Optimal collection goal is ≥ 5 to 6 million stem cells per kilogram of body weight
- For patients with MM, it is recommended to collect enough stem cells for 2 transplants



Minimizing the number of days of apheresis



Reaching the target collection of stem cells in the first mobilization attempt



Shortening the time to transplant

What are some factors that may affect the mobilization of stem cells?



Previous treatment regimens with drugs that are toxic to stem cells



Increased age



Type of disease

What is the minimum number of stem cells that need to be collected?

- Most transplant physicians prefer to collect at least 2 million stem cells per kilogram of body weight before proceeding to transplant
- Along with early collection, it is recommended to collect enough stem cells for 2 transplants for patients with MM
- Be sure to speak with your transplant team regarding your individual stem cell collection target as this can vary according to your disease, transplant center, and ability to collect sufficient cells
- On some occasions, too few stem cells are collected from the peripheral blood, which prevents you from proceeding to transplant. In these cases, you would generally take a short break before another mobilization attempt was made, termed *remobilization*

What are some commonly used mobilization options/strategies?

Growth factor alone

- There are several growth factors approved by the FDA that act to increase the number of circulating WBCs in the body
 - G-CSF is one of these approved growth factors

Chemotherapy followed by growth factor

- Chemotherapy, when used in combination with growth factors like G-CSF, is another mobilization strategy
- However, chemotherapy is not FDA approved for the mobilization of stem cells

Mozobil® (plerixafor) injection + G-CSF

- Mozobil is another agent that can be used to mobilize stem cells into the bloodstream for stem cell collection
- Mozobil is used in combination with G-CSF and can be used for patients with NHL or MM

The mobilization regimen you receive will be chosen by your transplant physician and may be tailored to fit your particular disease and other factors.

Important Safety Information (cont)

- Mozobil is not intended for hematopoietic stem cell transplantation (HSCT) mobilization and collection in patients with leukemia.
- Mozobil in combination with G-CSF increases circulating white blood cells (WBCs). Your WBC counts will be monitored.
- Thrombocytopenia (a decrease in the number of platelets circulating in the blood) has been observed in patients receiving Mozobil. Your platelet counts will be monitored.

Please see additional Important Safety Information in this piece and click [here](#) for full Prescribing Information.

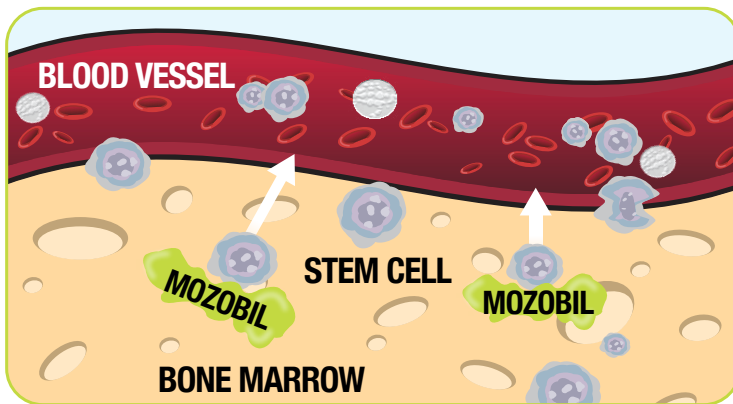
Chapter 3: Introduction to Mozobil® (plerixafor) injection

What are the approved uses for Mozobil?

Mozobil is approved by the FDA and can be used in combination with G-CSF for mobilization of stem cells into the bloodstream for collection and subsequent transplant in patients with NHL or MM.

What does Mozobil actually do?

- Mozobil releases the stem cells from the bone marrow into the bloodstream, allowing stem cells to be collected
- This enables your health care team to collect more stem cells during apheresis



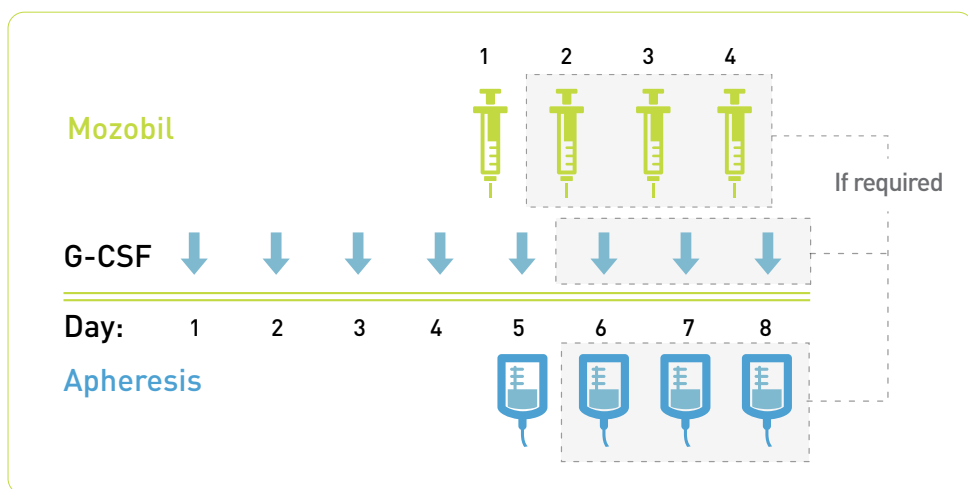
Important Safety Information (cont)

- Cancer cells may be released from the bone marrow and subsequently collected along with your stem cells during apheresis. The potential effects of infusing cancer cells during your transplant have not been well-studied.

Please see additional Important Safety Information in this piece and click [here](#) for full Prescribing Information.

What is the approved dose for Mozobil® (plerixafor) injection?

- Mozobil is given as an injection under the skin, known as a subcutaneous injection, approximately 11 hours before the start of each apheresis session
- Mozobil may be given for up to 4 days in a row, if needed
- Mozobil is used in combination with G-CSF. G-CSF is given every morning for 4 consecutive days before the first dose of Mozobil. If more than 1 day of apheresis is required, G-CSF will be continued each day along with Mozobil until apheresis is completed



You most likely will receive your Mozobil doses at your transplant center or hospital, depending on the decision of your transplant team.

Important Safety Information (cont)

- The most common adverse reactions (occurring in greater than or equal to 10% of patients) during HSC mobilization and apheresis were: diarrhea (37%), nausea (34%), tiredness (fatigue) (27%), injection site reactions (34%), headache (22%), pain in your joints (arthralgia) (13%), dizziness (11%), and vomiting (10%).

Please see additional Important Safety Information in this piece and click [here](#) for full Prescribing Information.

What Important Safety Information should I know about Mozobil[®] (plerixafor) injection?

- Severe, life-threatening allergic reactions (anaphylaxis) can happen in people who take Mozobil. Tell your doctor right away if you experience hives (itchy raised bumps), eye swelling, or trouble breathing.
- Mozobil is not intended for hematopoietic stem cell transplantation (HSCT) mobilization and collection in patients with leukemia.
- Mozobil in combination with G-CSF increases circulating white blood cells (WBCs). Your WBC counts will be monitored.
- Thrombocytopenia (a decrease in the number of platelets circulating in the blood) has been observed in patients receiving Mozobil. Your platelet counts will be monitored.
- Cancer cells may be released from the bone marrow and subsequently collected along with your stem cells during apheresis. The potential effects of infusing cancer cells during your transplant have not been well-studied.
- Your spleen may be examined if you experience pain in the left upper stomach area or left shoulder area as these may be signs of an enlarged or burst (ruptured) spleen.
- Mozobil can harm the unborn child when administered to a pregnant woman. Scientific studies have shown that Mozobil causes harm or death to unborn animals. If you are pregnant, your doctor should tell you about the potential risk to the fetus. If you are a female of childbearing potential you should use an effective form of contraception during treatment with Mozobil and for one week after the final dose.
- Breastfeeding is not recommended during treatment with Mozobil and for one week after the final dose.

Please see additional Important Safety Information in this piece and click [here](#) for full Prescribing Information.

How could Mozobil® (plerixafor) injection help?

Clinical studies have demonstrated several benefits to using Mozobil with G-CSF compared to G-CSF alone for the mobilization of stem cells. These included:

- Higher success rates for mobilizing stem cells
 - More patients achieved the minimum and target number of stem cells for a transplant
 - More patients collected stem cells and went on to stem cell transplant
- Fewer apheresis procedures

What should I tell my physician and/or transplant team before and/or while taking Mozobil?

- Severe or life-threatening allergic reactions can happen in people taking Mozobil. If you feel lightheaded or have difficulty breathing shortly after receiving your Mozobil injection, tell your physician or nurse immediately. Some patients have also experienced a sudden drop in their blood pressure when standing from a sitting position (orthostatic hypotension). Do not stand up abruptly on days when you are receiving Mozobil. These symptoms can occur during or shortly after Mozobil administration
- The most common side effects you may experience include diarrhea, nausea, vomiting, fatigue, redness and swelling at the injection site, pain in your joints, headache, and dizziness. It is important to let your transplant team know if you are having any of these side effects, even though most of these may improve or disappear after you finish receiving Mozobil injections
- Report to your transplant team immediately if you are having any left upper abdominal or left shoulder pain. These could possibly be signs of an enlarged spleen or ruptured spleen
- If you are a nursing mother, breastfeeding is not recommended during treatment with Mozobil and for one week after the final dose

Please see additional Important Safety Information in this piece and click [here](#) for full Prescribing Information.

Glossary

Absolute neutrophil count (ANC) – The real number of neutrophils present in a cubic milliliter of blood.

Apheresis – A procedure involving the collection of blood from a donor, the removal of one or more blood components (platelets or WBCs, for example), and the return of the rest of the blood to the donor.

Autologous stem cell transplant – A procedure in which the blood-forming stem cells are collected, stored, and later given back to the same person.

Bone marrow – A soft sponge-like tissue in the middle of most bones that produces RBCs, WBCs, and platelets.

Central venous catheter (CVC) – A tube passed into a large vein to monitor pressure, to administer medications or intravenous fluids, or to draw blood samples to perform tests. A CVC can be inserted into a vein located in the neck, chest, or groin.

Conditioning or preparative regimen – The treatments used to prepare a patient for stem cell transplantation. A conditioning regimen may include chemotherapy, antibody therapy, and/or radiation.

Cryopreservation – The process by which cells or tissue are preserved by cooling at very low temperatures.

Dimethylsulfoxide (DMSO) – A preserving agent used during the process of freezing stem cells. DMSO may cause side effects, such as taste of garlic, an unusual odor, nausea and vomiting, abdominal cramps, and chills.

Engraftment – The process in which transplanted stem cells travel through the blood to the bone marrow, where they begin to make healthy new blood cells. The definition of *engraftment* in transplant is very specific and relates to neutrophil and platelet count recovery. Neutrophil engraftment is defined as the first day of 3 consecutive days where the

neutrophil count (ANC) is 500 cells/mm³ (0.5 x 10⁹/L) or greater. Platelet engraftment is defined as 20,000/mm³ (20 x 10⁹/L) platelets unsupported for at least 7 days by a platelet transfusion.

Hematopoietic stem cells (HSCs) – A cell from which other types of cells develop. HSCs are found in the bone marrow and in the peripheral blood.

Hematopoietic stem cell transplant – A procedure in which blood-forming cells can be transferred back to oneself or from one person to another.

Mobilization – The process of stimulating stem cells to move out of the bone marrow and into the bloodstream for collection.

Multiple myeloma (MM) – A type of cancer in the plasma cells. Normal plasma cells are found in the bone marrow and are an important part of the immune system to help your body fight infection.

Neutrophils – The most common type of WBC; neutrophils are in charge of protecting the body against infection.

Non-Hodgkin's lymphoma (NHL) – A type of cancer that starts in WBCs and affects the body's lymphatic system, a part of the immune system that helps fight infections and some other diseases.

Platelets – A tiny round or oval disc found in the blood that helps in forming blood clots; platelets are essential to prevent excessive bleeding.

Red blood cells (RBCs) – Cells that carry oxygen to the body's tissues and carbon dioxide away from tissues.

Reinfusion – The process of reinjecting blood or other fluid into the body.

White blood cells (WBCs) – Cells that are part of the body's immune system and help fight infection and other disease.

Sample Mobilization and Transplant Calendar for a Patient With MM

Here is an example of a potential schedule for stem cell mobilization and transplant. This was a calendar for a patient who has MM and received Mozobil® (plerixafor) injection + G-CSF as their mobilization regimen. Talk to your transplant physician about your specific schedule.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Mobilization Days						
	Day 1: Start of G-CSF daily	Day 2: G-CSF daily	Day 3: G-CSF daily	Day 4: G-CSF daily Start Mozobil injection (11 hours before apheresis)	Day 5: G-CSF daily, if needed Mozobil injection, if needed First day of apheresis*	Day 6: Second apheresis day
Break Time: The number of days will depend on you and your transplant physician's preference						
*This patient required only 2 days of apheresis to collect enough stem cells after receiving Mozobil + G-CSF, however, you may need additional apheresis sessions to collect the minimum required number of stem cells.						
Transplant Procedure Days						
	Day -1: Conditioning/preparative regimen; Pre-transplant high-dose chemotherapy	Day 0: Stem cell transplant day Stem cells thawed and reinfused	Day +1:	Day +2:	Day +3:	Day +4:
Neutrophil and platelet counts are monitored						
Day +5:	Day +6:	Day +7:	Day +8:	Day +9:	Day +10: Engraftment process begins (time of normal engraftment is about 10 to 20 days)	Day +11:
Neutrophil and platelet counts are monitored						

As this is a patient who has MM, their transplant physician collected enough cells for **2 transplants** in case a second transplant was required. These extra cells will remain in storage and frozen until they are needed.

Please see additional Important Safety Information in this piece and click [here](#) for full Prescribing Information.

My Mobilization and Transplant Calendar

Here is a blank calendar to record your personal mobilization and transplant schedule after you have spoken to your transplant physician.

Month _____

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

Questions to Ask Your Transplant Physician

Please use this page to make note of anything you may want to discuss with your transplant physician at your next visit.

Question: _____

Response: _____

Question: _____

Response: _____

Question: _____

Response: _____

Question: _____

Response: _____

Additional Resources

- American Society for Blood and Marrow Transplantation (ASBMT): <http://www.asbmt.org>
- Blood & Marrow Transplant Information Network (BMT InfoNet): <http://www.bmtinfonet.org>
- Center for International Blood & Marrow Transplant Research (CIBMTR): <http://www.cibmtr.org>
- International Myeloma Foundation: <http://www.myeloma.org>
- Leukemia & Lymphoma Society: <http://www.lls.org>
- Leukemia Research Foundation: <https://www.allbloodcancers.org/>
- Lymphoma Research Foundation: <http://www.lymphoma.org>
- Mozobil® (plerixafor) injection website: <http://www.mozobil.com>
- Multiple Myeloma Research Foundation: <http://www.themmrf.org>
- National Bone Marrow Transplant Link (nbmtLink): <http://www.nbmtlink.org>
- National Marrow Donor Program (NMDP): <http://www.marrow.org>

Sanofi Is Committed to Helping Patients

Sanofi Patient Connection is a program connecting patients to medication and resources.

For additional information, please:



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call 1-888-847-4877



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