NCCN GUIDELINES FOR PATIENTS®

2018

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Chronic Myeloid Leukemia

Presented with support from:
NCCN National Comprehensive Cancer Network FOUNDATION®
Guiding Treatment, Changing Lives.

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LEARNING that you have cancer can be overwhelming.

Learning that you have cancer can be overwhelming. The goal of this book is to help you get the best care. It presents which cancer tests and treatments are recommended by experts in chronic myeloid leukemia.

The National Comprehensive Cancer Network® (NCCN®) is a not-for-profit alliance of 27 of the world's leading cancer centers. Experts from NCCN have written treatment guidelines for doctors who treat chronic myeloid leukemia. These treatment guidelines suggest what the best practice is for cancer care. The information in this patient book is based on the guidelines written for doctors.

This book focuses on the treatment of chronic myeloid leukemia. Key points of the book are summarized in the NCCN Quick Guide™. NCCN also offers patient books on classic myeloproliferative neoplasms, myelodysplastic syndromes, lymphoma, and other cancer types. Visit NCCN.org/patients for the full library of patient books, summaries, and other resources.

About

National Comprehensive Cancer Network®

These patient guidelines for cancer care are produced by the National Comprehensive Cancer Network® (NCCN®).

The mission of NCCN is to improve cancer care so people can live better lives. At the core of NCCN are the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). NCCN Guidelines® contain information to help health care workers plan the best cancer care. They list options for cancer care that are most likely to have the best results. The NCCN Guidelines for Patients® present the information from the NCCN Guidelines in an easy-to-learn format.

Panels of experts create the NCCN Guidelines. Most of the experts are from NCCN Member Institutions. Their areas of expertise are diverse. Many panels also include a patient advocate. Recommendations in the NCCN Guidelines are based on clinical trials and the experience of the panelists. The NCCN Guidelines are updated at least once a year. When funded, the patient books are updated to reflect the most recent version of the NCCN Guidelines for doctors.

For more information about the NCCN Guidelines, visit NCCN.org/clinical.asp.

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NCCN FOUNDATION®
Guiding Treatment, Changing Lives.

NCCN Foundation was founded by NCCN to raise funds for patient education based on the NCCN Guidelines. NCCN Foundation offers guidance to people with cancer and their caregivers at every step of their cancer journey. This is done by sharing key information from leading cancer experts. This information can be found in a library of NCCN Guidelines for Patients® and other patient education resources. NCCN Foundation is also committed to advancing cancer treatment by funding the nation's promising doctors at the center of cancer research, education, and progress of cancer therapies.

For more information about NCCN Foundation, visit NCCNFoundation.org.

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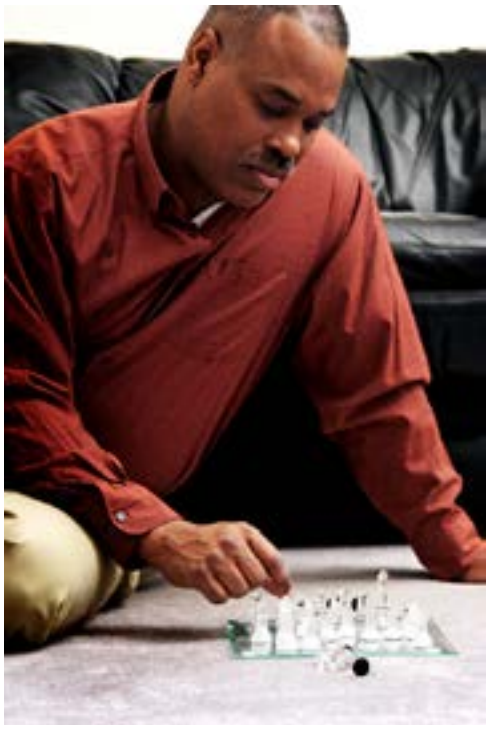
LLS is dedicated to developing better outcomes for blood cancer patients through research, education and patient services and is happy to have this comprehensive resource available to patients. LLS.org/informationspecialists.




I can't
do it

Contents

How to use this book

Who should read this book?

This book is about treatment for adults with chronic myeloid leukemia. This leukemia is called CML, for short. Patients and those who support them—caregivers, family, and friends—may find this book helpful. It is a good starting point to learn what your options may be.

Are the book chapters in a certain order?

Early chapters explain concepts that are repeated in later chapters. **Part 1** explains what CML is. Knowing more about this leukemia may help you better understand its treatment.

Parts 2 through 6 address issues related to treatment. **Part 2** lists which health tests are needed before treatment. **Part 3** briefly describes the main types of treatments so you can understand your options that are listed in **Parts 4** and **5**. Tips for making treatment decisions are presented in **Part 6**.

Does this book include all options?

This book includes information for many people. Your treatment team can point out what applies to you. They can also give you more information. While reading, make a list of questions to ask your doctors.

The treatment options are based on science and the experience of NCCN experts. However, their recommendations may not be right for you. Your doctors may suggest other options based on your health and other factors. If other options are given, ask your treatment team questions.

Help! What do the words mean?

In this book, many medical words are included. These are words that your treatment team may say to you. Most of these words may be new to you. It may be a lot to learn.

Don't be discouraged as you read. Keep reading and review the information. Ask your treatment team to explain a word or phrase that you do not understand.

Words that you may not know are defined in the text or in the *Dictionary*. Acronyms are also defined when first used and in the *Glossary*. Acronyms are short words formed from the first letters of several words. One example is DNA for **d**eoxyribo**n**ucleic **a**cid.

1
CML basics

You've learned that you have or may have a blood cancer. It's common to feel shocked and confused. Part 1 reviews some basics that may help you learn about CML.

Blood

To learn about CML (**c**hronic **m**yeloid **l**eukemia), you first must know about blood. Blood is one of the fluids in the body. It consists of blood cells that move within plasma. Plasma is mostly water.

Blood cells

There are three main types of blood cells. One type is red blood cells (also called erythrocytes). Another type is white blood cells (leukocytes). The third type is platelets (thrombocytes).

Blood cells have important jobs. Red blood cells carry oxygen throughout the body. White blood cells help fight germs. Platelets help control bleeding.

Your blood cells don't live forever. Many have a short lifespan. Thus, blood cells are being replaced in your body all the time.

Blood cell formation

Most blood cells are formed in bone marrow. Bone marrow is the sponge-like tissue in the center of most bones. **See Figure 1**.

Within your bone marrow are blood-forming cells. Blood stem cells are the cells from which all blood cells are formed. They are also called hematopoietic stem cells. As shown in **Figure 2**, they start the family tree of blood cells.

Blood stem cells can make exact copies of themselves. They can also make new cells that are a step closer to being a blood cell. These cells are called progenitor cells. Compared to stem cells, progenitor cells are set to become a certain type of blood cell.

There are two types of blood progenitor cells. Lymphoid progenitor cells start one branch of the family tree. Myeloid progenitor cells start another branch.

At the end of the lymphoid branch is a type of white blood cell called lymphocytes. There are three types of lymphocytes. They are NK cells, B cells, and T cells. Lymphocytes are released from bone marrow into the bloodstream.

At the end of the myeloid branch are white blood cells, red blood cells, and platelets. These white blood cells are called granulocytes. Granulocytes include neutrophils, eosinophils, and basophils. Red blood cells, platelets, and granulocytes are released from bone marrow into the bloodstream.

Figure 1
Bone marrow

Bone marrow is the sponge-like tissue in the center of most bones. Most blood cells are formed in bone marrow.

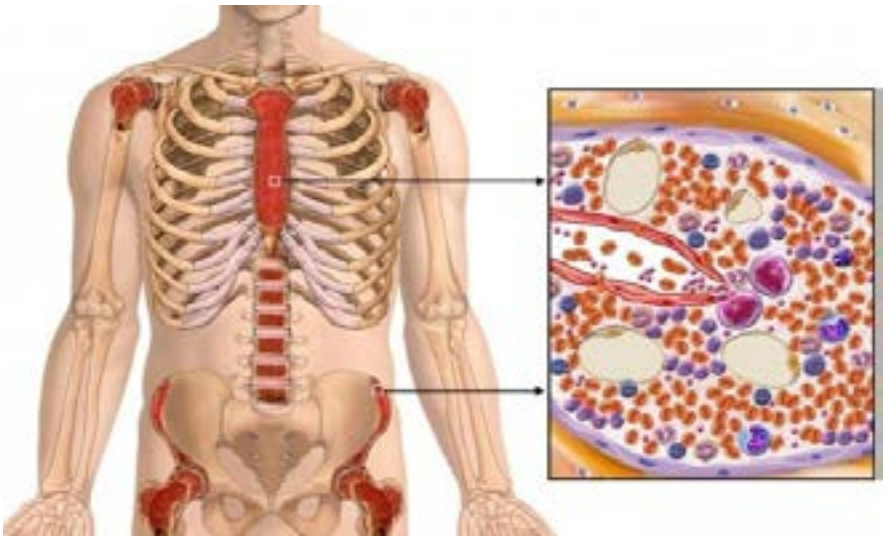
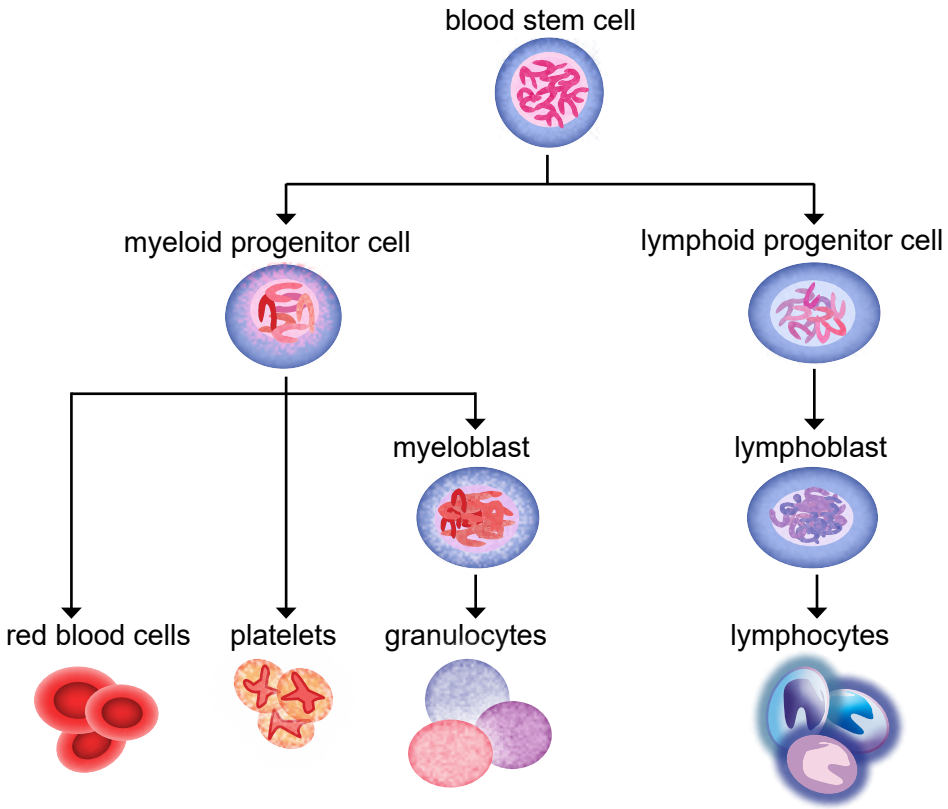


Figure 2
Blood cells

Blood (hematopoietic) stem cells are the cells from which all blood cells are formed. They make two types of progenitor cells. Common lymphoid progenitor cells form into white blood cells called lymphocytes. Common myeloid progenitor cells form into red blood cells, platelets, and white blood cells called granulocytes.



A disease of cells

Your body is made of trillions of cells. Cancer is a disease of cells. Each type of cancer is named after the cell from which it is derived.

Cell of origin

MPNs (**m**yelo**p**roliferative **n**eoplasms) are a group of rare blood cancers. They are cancers that derive from blood-forming stem cells within the myeloid branch. “Myelo” means marrow. “Proliferative” means growing and refers to making too many cells. A neoplasm is any abnormal growth. MPNs have too many blood-forming cells in the marrow. In turn, there are also too many blood cells.

CML is a type of MPN. The cell that is affected is a stem cell that makes granulocytes. Thus, there is an excess of white blood cells, in particular neutrophils. Other cell counts that can be high include basophils and eosinophils. “Chronic” means this cancer worsens slowly.

The cause of CML

Cells have a control center called the nucleus. The nucleus contains chromosomes, which are long strands of DNA (**d**eoxyribo**n**ucleic **a**cid) tightly wrapped around proteins. **See Figure 3**. Within DNA are coded instructions for building new cells and controlling how cells behave. These instructions are called genes.

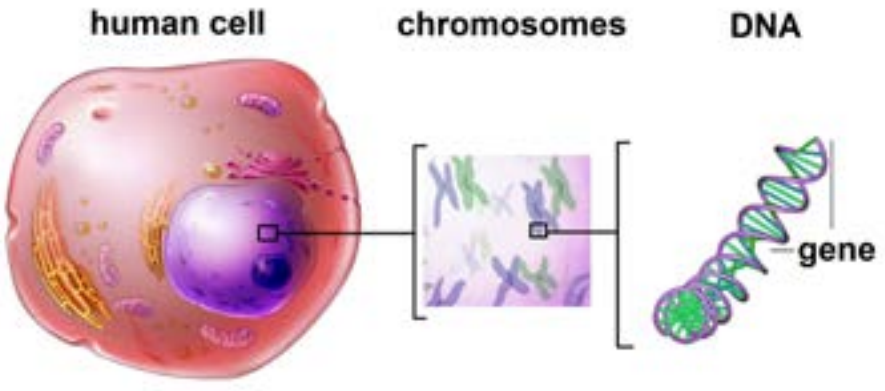
There are often abnormal changes in genes within cancer cells. These abnormal changes are called mutations. Mutations cause cancer cells to not behave like normal cells. Also, mutations sometimes cause cancer cells to look very different from normal cells. The mutation that causes CML is the *BCR-ABL1* gene. It is explained next.

Philadelphia chromosome

A cell must make a copy of its chromosomes before dividing into 2 cells. Sometimes, there are mistakes in the copies. One type of mistake is when parts of two chromosomes switch with each other. This is called a translocation. It can result in a fusion gene.

Figure 3
Genetic material in cells

Most human cells contain the “blueprint of life”—the plan by which our bodies are made and work. The plan is found inside of chromosomes, which are long strands of DNA that are tightly wrapped around proteins. Genes are small pieces of DNA that contain instructions for building new cells and controlling how cells behave. Humans have an estimated 20,000 to 25,000 genes.



BCR-ABL1 is a fusion gene. It is not found in normal blood cells. It is not passed down from parents to children. It codes for a protein that causes too many granulocytes to be made. These granulocytes aren't normal. They don't mature and don't die as they should.

BCR-ABL1 is formed by a translocation between chromosomes 9 and 22. **See Figure 4**. Chromosome 9 has the *ABL* gene. During the translocation, the *ABL* gene attaches to chromosome 22. This abnormal chromosome 22 is called the Philadelphia chromosome.

The Philadelphia chromosome is the hallmark of CML. It contains the *BCR-ABL1* gene. If you do not have the Philadelphia chromosome or the *BCR-ABL1* gene, you do not have CML.

Three phases

There are three phases of CML. They are called chronic, accelerated, and blast phases. They are based on the number of blasts in the blood and marrow.

Blasts are early forms of blood cells. They are stem cells that can't become normal, mature cells. Most cases of CML don't have high blast counts. High numbers of blasts are a sign of more advanced phases of CML.

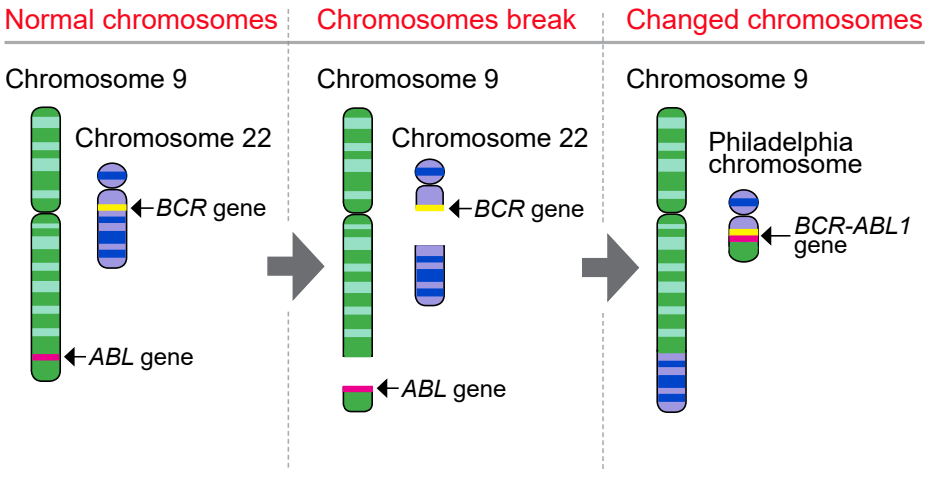
Chronic phase

The first phase of CML is called the chronic phase. In this phase, there is an increased number of white blood cells in the blood, marrow, or both. Less than 10 out of every 100 blood cells are blasts (<10%).

Most often, there are no cancer symptoms in the chronic phase. If present, symptoms are often mild. You may have fatigue. You may have a feeling of

Figure 4
Philadelphia chromosome

The Philadelphia chromosome is formed by a translocation between parts of chromosomes 9 and 22. It contains the abnormal *BCR-ABL1* fusion gene.



fullness under the left side of the ribs. Your body can still fight germs since blood counts are close to normal.

CML progresses very slowly in the chronic phase. It may take several months or years to reach the next phase. Compared to other phases, CML in the chronic phase tends to respond better to treatment.

Accelerated phase

The second phase of CML is called the accelerated phase. In this phase, the number of blasts is higher than normal. The number of white blood cells is also high. There may also be a very low number of platelets in the blood.

In all phases, CML cells contain the Philadelphia chromosome. However, in the accelerated phase, there may be new abnormal changes within chromosomes.

In the accelerated phase, CML cells may grow fast. You may have symptoms. Such symptoms may include fever, weight loss without dieting, and not feeling hungry. You may also have an enlarged spleen.

Blast phase

The third and final phase of CML is called blast phase. It is also referred to as “blast crisis.” Once CML is in blast phase, it can be life-threatening.

In the blast phase, the number of blasts is very high. The blasts may have spread outside the blood or marrow to other tissues. Symptoms are common. They may include infections, bleeding, belly pain, and bone pain.

CML cells become more abnormal. They often act like acute leukemia. Acute leukemia worsens very fast. Types of acute leukemia are AML (**a**cute **m**yeloid **l**eukemia) and ALL (**a**cute **l**ymphoblastic **l**eukemia).

Review

- Most blood cells are formed in bone marrow. Blood (hematopoietic) stem cells are the cells from which all blood cells are formed.
- MPNs are a group of rare blood cancers. CML is a type of MPN. It affects blood stem cells that make granulocytes.
- There are 3 phases of CML. The chronic phase is the first phase. The accelerated phase is the second phase. The third and final phase is called the blast phase.

2
Testing for CML

Your doctor may think you have a blood cancer. Part 2 describes the tests used to diagnose CML and plan treatment. Some of these tests may also be used to check treatment results.

Medical history

Your medical history includes any health events and medicines you've taken in your life. You will be asked about illnesses, injuries, health conditions, and more. It may help to make a list of old and new medications while at home to bring to your doctor's office.

Some cancers and other health conditions can run in families. Thus, your doctor will ask about the medical history of your blood relatives. You doctor may ask about the health of your siblings, your parents and their siblings, and your grandparents and their siblings. Be prepared to tell who in your family has had what diseases and at what ages.

A medical history is needed for diagnosis and treatment planning. See Guide 1 for a complete list of care that is advised prior to treatment.

Physical exam

Doctors often perform a physical exam along with taking a medical history. A physical exam is a study of your body for signs of disease. To start, your basic body functions will be measured. These functions include your temperature, blood pressure, and pulse and breathing (respiration) rate. Your weight will also be checked.

During the exam, your doctor will listen to your lungs, heart, and gut. Your doctor will also look at and feel parts of your body. This is done to see if organs are of normal size, are soft or hard, or cause pain when touched.

Cancer and other health conditions can cause organs to become enlarged and hard. With CML, your spleen may be larger than normal. The spleen is a small organ to the left of your stomach. It filters blood, stores blood cells, and destroys old blood cells.

Blood tests

Blood tests are useful for diagnosing CML. They can help to find other diseases, too. They require a sample of your blood. Samples of blood can be removed with a blood draw.

Blood draw

Before a blood draw, you might need to stop drinking and eating for several hours. A needle will be inserted into your vein to remove blood. Your blood sample will be sent to a lab. A pathologist will perform the blood tests. A pathologist is a doctor who's an expert in testing cells to find disease.

CBC with differential

A CBC (**c**omplete **b**lood **c**ount) measures parts of the blood. It is often done with a machine. Test results include counts of white blood cells, red blood cells, and platelets. Your blood counts may be low or high because of cancer or another health problem. It is an essential test that gives a picture of your overall health.

There are several types of white blood cells. A differential counts the number of each type of cell. It also checks if the counts are in balance with each other. Your doctor can determine the cause of an abnormal white blood count from this test.

Chemistry profile

Chemicals in your blood come from your liver, bone, and other organs. A chemistry profile measures the levels of these chemicals. Abnormal results may be a sign that an organ or body system isn't working well. Such organs include your liver and kidneys. This test may be repeated during and after treatment to assess results.

Guide 1. Tests for CML

Test name
• Medical history
• Physical exam
• CBC with differential
• Chemistry profile
• Bone marrow aspiration and biopsy
• Cytogenetics for Philadelphia chromosome
• QPCR for *BCR-ABL1* gene
• Hepatitis panel

Bone marrow exam

A bone marrow exam removes cells from your bones for testing. Test results will be used to confirm the disease phase. A bone marrow exam may also be done during treatment to check results.

Aspiration and biopsy

A bone marrow exam consists of two procedures. A bone marrow aspiration removes a small amount of liquid bone marrow. A bone marrow biopsy removes a sample of bone and soft bone marrow.

Often, these procedures are done at the same time. They are performed on the back of the hip bone. You may receive a light sedative beforehand.

You will likely lie on your side as shown in **Figure 5**. Some people lie on their belly. Your doctor will first clean and numb your skin.

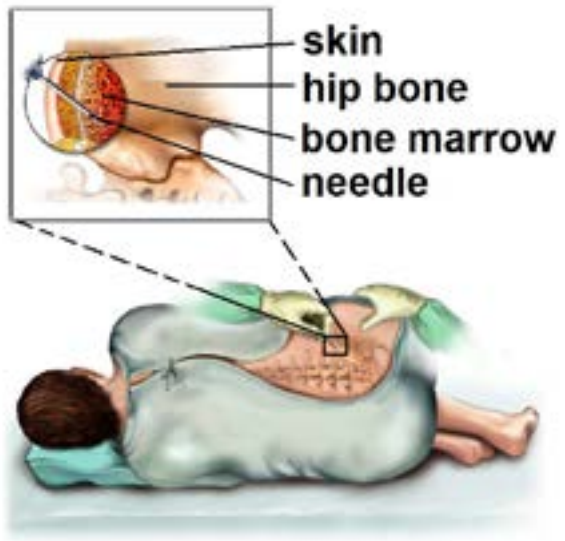
For aspiration, a hollow needle will be inserted into your skin and pushed into the bone. Liquid bone marrow will then be drawn into a syringe. For the biopsy, a wider needle will be inserted into your bone and rotated to remove a core sample. You may feel bone pain during and after the procedures for a few days. Your skin may bruise.

Lab tests

The samples will be sent to a lab for testing. A pathologist will study the samples with a microscope. He or she will assess the number of cells and how they look. This information is used to determine the CML phase. Genetic tests will also be done.

Figure 5
Bone marrow exam

A bone marrow exam removes a sample of bone and marrow for testing. The procedure is often done on the back of the hip.



Genetic tests

Genetic tests for CML are done on leukemia cells. They assess for abnormal changes in genes and chromosomes. Such changes are not present at birth. Genetic tests are performed by pathologists. It often takes several days before the lab results are known.

Bone marrow cytogenetics

Cytogenetics is the study of chromosomes. It is used to confirm CML by testing for the Philadelphia chromosome. The pathologist will also look for other abnormal chromosomes. This will help define the CML phase.

Cytogenetics may be used to assess treatment results. Treatment is working well if tests show the abnormal chromosomes are no longer present. Abnormal chromosomes reappear when treatment stops working.

Karyotype

A karyotype is a picture of the chromosomes in cells. **See Figure 6**. For CML, a sample of bone marrow should be used. A chemical will be added to the marrow sample to start cell growth. Then, the cells will be studied with a microscope.

FISH

FISH (**f**luorescence **i**n **s**itu **h**ybridization) may be performed if a karyotype can't be done. It can assess for the *BCR-ABL1* gene to confirm CML. FISH is sometimes used to assess treatment response if other tests can't be done.

FISH involves special color dyes—called probes. The probes attach to the *BCR* gene and the *ABL* gene. The *BCR-ABL1* gene is detected when the colors of the probes overlap. This test can be performed on either a bone marrow or blood sample.

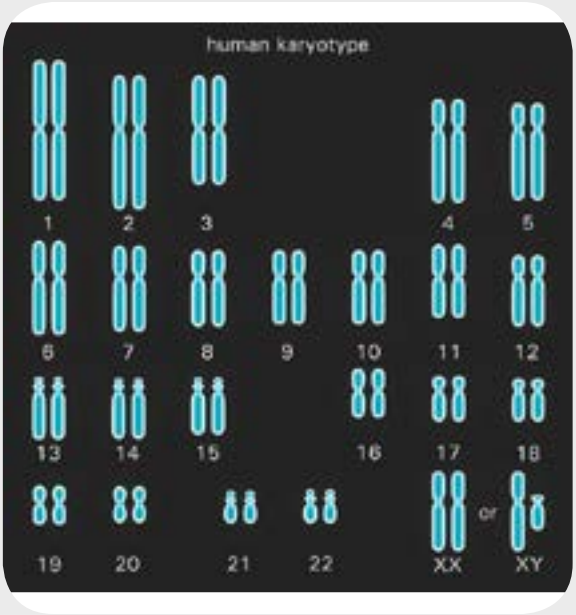
QPCR-IS

QPCR (**q**uantitative reverse transcriptase-**p**olymerase **c**hain **r**eaction) is a test used to assess for the *BCR-ABL1* gene. This test can be performed on a sample of blood or bone marrow. It is very sensitive. It can find one CML cell among more than 100,000 normal cells.

A lab that uses the IS (**I**nternational **S**cale) is advised. IS is a standardized method for measuring and reporting QPCR scores. If IS can't be used, it is harder to compare test results from different labs. In this case, test results from the same lab is advised. Read page 29 to learn more about the IS.

Figure 6
Karyotype

A karyotype is a picture of the chromosomes in cells. It shows abnormal changes in chromosomes.



Hepatitis panel

Hepatitis B can be an important factor in the treatment of CML. Hepatitis B can become active again due to the cancer or some of its treatments. Thus, tell your treatment team if you've ever been infected with hepatitis. If you're unsure, testing is advised. A sample of your blood is needed for testing.

Review

- A medical history is a report of all health events in your lifetime. It will include questions about your family's health, too.
- Your doctor will examine your body for signs of disease. He or she will touch parts of your body to see if anything feels abnormal.
- Blood tests assess the parts of your blood. Your doctor will use the blood results to help decide if and what type of disease is present.
- A bone marrow exam removes bone and marrow for testing.
- Genetic tests assess for abnormal changes in chromosomes and genes. Results can help your doctor identify a disease and plan treatment.
- Testing for hepatitis B may be done since it can become active again.

3
Overview of cancer treatments

Part 3 describes the main types of treatment for CML. Knowing what a treatment is will help you understand your treatment options listed in Part 4 or Part 5. There is more than one treatment for CML. Not every person will receive every treatment described in this chapter.

Tyrosine kinase inhibitors

Guide 2 lists the TKIs (**t**yrosine **k**inase **i**nhibitors) used to treat CML. They are a standard treatment. TKIs belong to a class of drugs called targeted therapy. These drugs affect molecules that help cancer cells grow. Many targeted therapies stop the signals that tell a cell to grow.

How TKIs work

The protein made by the *BCR-ABL1* gene is a tyrosine kinase. It moves chemicals, called phosphates, from one molecule to another. The phosphate "turns on" the next molecule in the signal pathway. TKIs block the transfer of phosphase and in turn stop growth signals. **See Figure 7**.

Each TKI works in a slightly different way. You may start with one drug that may not work or stop working over time. The latter often occurs when there's a new mutation in CML cells. Switching to a different TKI that works against the mutation may help.

Imatinib

Imatinib was the first TKI approved by the U.S. FDA (**F**ood and **D**rug **A**dministration) to treat CML. Thus, it is called a "first-generation" TKI. It attaches to the inactive site on the BCR-ABL1 protein to stop growth signals.

Dasatinib

Dasatinib is a second-generation TKI. Dasatinib is more potent than imatinib. It attaches to active and inactive sites on the BCR-ABL1 protein to block growth signals. It works against most *BCL-ABL1* mutations. It also blocks SCR, PDGFR, and KIT kinases.

Nilotinib

Nilotinib is a second-generation TKI. It works in almost the same way as imatinib. However, nilotinib is more potent. It works against most *BCL-ABL1* mutations. It also blocks PDGFR and KIT kinases.

Guide 2. TKIs for CML

Generic (chemical) name	Brand name (sold as)	Generation
Imatinib	Gleevec®	First
Dasatinib	Sprycel®	Second
Nilotinib	Tasigna®	Second
Bosutinib	Bosulif®	Second
Ponatinib	Iclusig®	Third

Bosutinib
Bosutinib is a second-generation TKI. It attaches to active and inactive sites on the BCR-ABL1 protein to block growth signals. It works against most *BCL-ABL1* mutations. It also blocks SCR kinases.

Ponatinib
Ponatinib is third-generation TKI. It blocks many tyrosine kinases including BCR-ABL1. It works against all *BCL-ABL1* mutations including *T315I*.

What to expect

TKIs for CML are alike in many ways. They are made in the form of a pill that is swallowed. You will need to avoid certain medicines, food, and drinks, such as grapefruit juice. Ask your treatment team for more information on how to take your TKI.

Side effects
A side effect is an unhealthy or unpleasant physical or emotional condition caused by treatment. Not every person gets the same side effects. Side effects depend on the drug, the amount taken, the length of treatment, and the person.

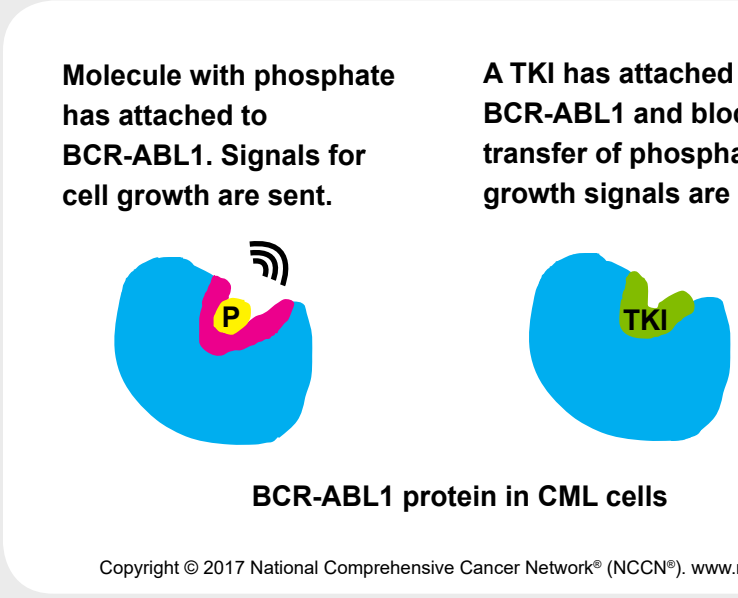
There are side effects common among TKIs. These include low blood counts. You may feel nauseated, have diarrhea, and vomit. Changes in your skin may occur, such as a rash. You may feel tired and get headaches and fevers. Fluid buildup in limbs or around certain organs may occur.

All TKIs can cause severe side effects. Your doctor will monitor your safety. Severe side effects include heart problems, liver problems, and kidney failure. Do not take TKIs while pregnant or breastfeeding.

Not all side effects of TKIs are listed here. Please ask your treatment team for a complete list of common and rare side effects. If a side effect bothers you, tell your treatment team. There may be ways to help you feel better. There are also ways to prevent some side effects.

Figure 7
How TKIs work

Kinases move chemicals, called phosphates, from one molecule to another. The phosphate "turns on" the next molecule in the signal pathway. TKIs block the transfer of phosphate and in turn stop cell growth signals.



Chemotherapy

Chemotherapy, or “chemo,” includes drugs that disrupt the life cycle of cancer cells. The types of chemotherapy differ in the way they work. Some kill cancer cells by damaging their DNA or by disrupting the making of DNA. Others interfere with cell parts that are needed for making new cells. Thus, no new cells are made to replace dying cells. Chemotherapy can affect both cancer and normal cells.

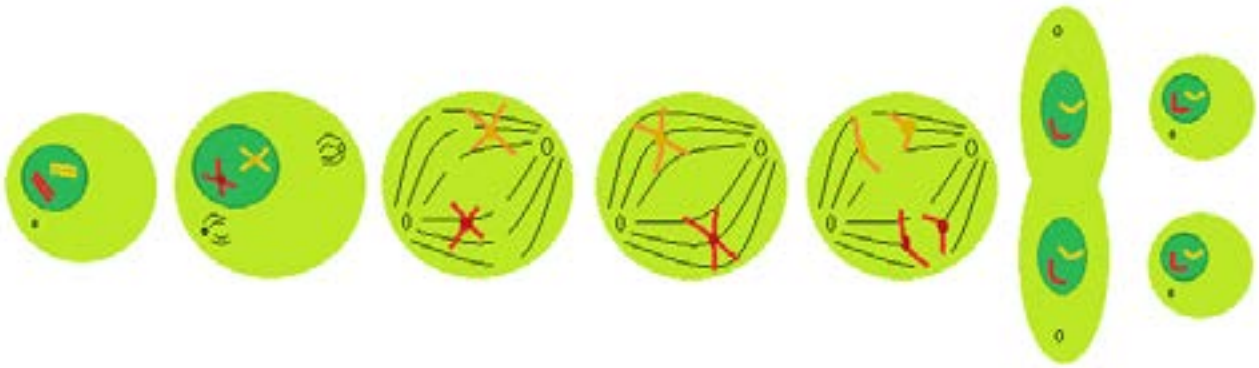
Some chemotherapy drugs work when cells are in an active growth phase. **See Figure 8**. During the active growth phase, cells grow and divide to form a new cell. Chemotherapy that disrupts the growth phase works well for cancer cells that are growing and dividing quickly. Other chemotherapy drugs work in any growth or resting phase.

What to expect

Chemotherapy may consist of one or more drugs. When only one drug is used, it is called a single agent. However, not all drugs work the same way, so often more than one drug is used. A combination regimen is the use of two or more chemotherapy drugs.

Figure 8
Chemotherapy and the cell cycle

A cell goes through many changes to divide into two cells. Science has grouped these changes into 7 main phases. There may be another phase of rest, too. Some chemotherapy drugs work in any phase. Other chemotherapy drugs work in one or two growth phases. In growth phases, DNA is copied and two full sets of chromosomes are made. A full set of chromosomes is pulled into each end of the cell. The cell then divides into two cells each with their own set of chromosomes.



Chemotherapy may work in some or all phases of cell division.

Omacetaxine is the newest chemotherapy for CML. It is active against all of the mutations that make TKI not work. It is used for advanced phases of CML. Read Part 5 for more information.

Omacetaxine is given as a liquid that is injected under the skin with a needle. Other chemotherapy drugs may be injected into a vein. Or, they may be given as a pill that is swallowed.

Chemotherapy is given in cycles of treatment days followed by days of rest. This allows your body to recover before the next cycle. Cycles vary in length depending on which drugs are used. Often, a cycle is 14, 21, or 28 days long. If you will have chemotherapy, ask your doctor how many cycles will be given. Also ask how many days of treatment there are within a cycle.

Side effects

Side effects of chemotherapy depend on multiple factors. These factors include the drug type, amount taken, length of treatment, and the person. In general, side effects are caused by the death of fast-growing cells.

Fast-growing cells are found in the hair follicles, gut, mouth, and blood. Death of these cells can cause low blood cell counts, not feeling hungry, nausea, vomiting, diarrhea, hair loss, and mouth sores.

Most side effects appear shortly after treatment starts and will stop after treatment. However, other side effects are long-term or may appear years later. Late side effects include another type of cancer, heart disease, and problems having babies (infertility).

Not all side effects of chemotherapy are listed here. Please ask your treatment team for a complete list of common and rare side effects. If a side effect bothers you, tell your treatment team. There may be ways to help you feel better. There are also ways to prevent some side effects.

Supportive care

Supportive care doesn't aim to treat cancer but aims to improve quality of life. It is also called palliative care. It can address many needs. One example is treatment for physical and emotional symptoms. Supportive care can also help with treatment decisions as you may have more than one option. It can also help with coordination of care between health providers. Talk with your treatment team to plan the best supportive care for you.

Hematopoietic cell transplant

Blood (hematopoietic) stem cells are cells from which all blood cells are formed. They mainly exist in bone marrow. Cancer or its treatment can damage or destroy blood stem cells.

A stem cell transplant replaces damaged or destroyed stem cells with healthy stem cells. An allogeneic stem cell transplant uses healthy stem cells from a donor. The donor may be related to you or not. This transplant is also called an allogeneic HCT (**h**ematopoietic **c**ell **t**ransplant).

The healthy stem cells will form into new marrow and blood cells. This creates a new immune system. Another benefit of this transplant is the GVL (**g**raft-**v**ersus-**l**eukemia) effect. The GVL effect is an attack on cancer cells by the transplanted stem cells. The steps of an allogeneic HCT are briefly described next.

HLA typing

Special testing must be done to find the right donor for you. The donor and your tissue type must be a near-perfect match for this treatment to work. The test used to check tissue type is called HLA (**h**uman **l**eukocyte **a**ntigen) typing. A blood sample is needed to perform the test.

Conditioning

Before the transplant, you will receive treatment that destroys bone marrow cells. The death of the cells creates room for the healthy stem cells. It also weakens your immune system so your body won't kill the transplanted cells.

There are two main types of conditioning treatment. High-dose conditioning consists of high doses of strong chemotherapy. Reduced-intensity conditioning consists of low doses of strong chemotherapy. It may also consist of low-intensity drugs. Radiation therapy may also be given as part of conditioning treatment.

High-dose conditioning can cause very bad side effects. It can be deadly. Also, not everybody can tolerate it. Your doctor will decide if you are healthy enough for this treatment. Reduced-intensity conditioning may be used for people who are older or less healthy overall. However, the chance for a cancer relapse is greater.

Transplanting stem cells

After chemotherapy, you will receive the healthy stem cells through a transfusion. A transfusion is a slow injection of blood products through a central line into a large vein. A central line (or central venous catheter) is a thin tube. The tube will be inserted into your skin through one cut and into your vein through a second cut. Local anesthesia will be used. This process can take several hours to complete.

The transplanted stem cells will travel to your bone marrow and grow. New, healthy blood cells will form. This is called engraftment. It usually takes about 2 to 4 weeks.

Until then, you will have little or no immune defense. You may need to stay in a very clean room at the hospital. You may be given antibiotics to prevent or treat infection. You may also be given a red blood cell transfusion to prevent bleeding and to treat anemia. Platelet transfusion may be received to treat a low platelet count or bleeding. While waiting for the cells to engraft, you will likely feel tired and weak.

Clinical trials

One of your treatment choices may be to join a clinical trial. Joining a clinical trial is strongly supported. NCCN believes that you will receive the best management in a clinical trial.

New tests and treatments aren't offered to the public as soon as they're made. They first need to be studied. A clinical trial is a type of research that studies a test or treatment in people.

Clinical trials study how safe and helpful tests and treatments are for people. When found to be safe and helpful, they may become tomorrow's standard treatment. Because of clinical trials, the tests and treatments in this book are now widely used to help people with leukemia. Future tests and treatments that may have better results will depend on clinical trials.

New tests and treatments go through a series of clinical trials. These trials aim to ensure they're safe and work. Without clinical trials, there is no way to know if a test or treatment is safe or helpful. Clinical trials have four phases. Some examples of the four phases of treatment are:

- **Phase I trials** aim to find the safest and best dose of a new drug. Another aim is to find the best way to give the drug with the fewest side effects. These trials often involve about 20 people.
- **Phase II trials** assess if a drug works for a specific type of cancer. These trials often involve 20 to 100 people.
- **Phase III trials** compare a new drug to a standard treatment head-to-head. These trials often involve hundreds or thousands of people.
- **Phase IV trials** test drugs approved by the U.S. FDA to learn more about side effects with long-term use.

Joining a clinical trial has benefits. First, you'll have access to the most current cancer care. However, please note that it is unknown how well new treatments work if at all. Second, you will receive the best management of care. Third, the results of your treatment—both good and bad—will be carefully tracked. Fourth, you may help other people who will have cancer in the future.

Clinical trials have risks, too. Like any test or treatment, there may be side effects. Also, new tests or treatments may or may not improve your health. In fact, your health may worsen during a trial. Other downsides may include more hospital trips, paperwork, and extra costs for you.

To join a clinical trial, you must meet the conditions of the study. Patients in a clinical trial are often alike in terms of their cancer and general health. Thus, if patients improve, it's because of the treatment and not because of differences between them.

To join, you'll need to review and sign an informed consent form. This form describes the study in detail. The study's risks and benefits should be described and may include others than those described above.

Ask your treatment team if there is an open clinical trial that you can join. There may be clinical trials where you're getting treatment or at other treatment centers nearby. You can also find clinical trials through the websites listed in Part 6.

Review

- TKIs are a standard treatment of CML. They stop growth signals sent by the BCR-ABL1 protein.
- Chemotherapy stops the life cycle of cancer cells so they can't increase in number.
- Allogeneic HCT replaces your blood stem cells with donor stem cells, which in turn make a new immune system and attack the CML cells.
- Clinical trials give people access to new tests and treatments that otherwise can't usually be received. These new tests and treatments may in time be approved by the FDA.

Complementary and alternative medicine

CAM (**c**omplementary and **a**lternative **m**edicine) is a group of treatments that aren't often given by doctors. There is much interest today in CAM for cancer. Many CAMs are being studied to see if they are truly helpful.

Complementary medicines are treatments given along with usual medical treatments. While CAMs aren't known to kill cancer cells, they may improve your comfort and well-being. Two examples are acupuncture for pain management and yoga for relaxation.

Alternative medicine is used in place of usual medicine. Some alternative medicines are sold as cures even though they haven't been proven to work in clinical trials. If there was good proof that CAMs or other treatments cured cancer, they would be included in this book.

It is important to tell your treatment team if you are using any CAMs. They can tell you which CAMs may be helpful and which CAMs may limit how well medical treatments work.

4
Treatment guide: Chronic phase

Part 4 is a treatment guide for the chronic phase of CML. It starts with explaining the risk groups used to plan treatment. Next, the first treatments recieved are listed. Then, monitoring and second-line treatment are explained. Your doctor may suggest other options based on your health and wishes. Fully discuss your options with your doctor.

Risk groups

Your doctor will plan your treatment based on many factors. These factors include your health history and treatment side effects. Another factor is the outlook (prognosis) of the leukemia.

Sokal and Hasford risk scores

- Low-risk group
  - Sokal score is less than 0.8
  - Hasford score is 780 or less
- Intermediate-risk group
  - Sokal score is between 0.8 and 1.2
  - Hasford score is between 781 and 1480
- High-risk group
  - Sokal score is greater than 1.2
  - Hasford score is greater than 1480

Scoring systems that predict prognosis have been made. Such systems include the Sokal and Hasford scores. Using one of these, your doctor will calculate your risk score. The score is based on your age, spleen size, and blood counts.

Based on the risk score, you will be assigned to the low-, intermediate-, or high-risk group. People in the same risk group will likely respond to treatment in the same way. Thus, doctors often use risk groups to help plan treatment. Ask your doctor how your risk group affects your treatment.

First-line treatment

In general, there are two main goals of treatment. One goal is to control the leukemia so tests don't detect any signs of the disease. The other goal is to stop CML from progressing to an advanced phase.

Guide 3 lists first-line treatment options for the chronic phase. TKIs top the list. They are often very good at controlling CML for long periods of time. Research suggests that dasatinib and nilotinib may work better for intermediate- or high-risk groups.

Guide 3. First-line treatment

What are the options?
• Imatinib
• Dasatinib or nilotinib
• Clinical trial

Monitoring

It's important to monitor the treatment response. This is done by testing a blood sample by QPCR. QPCR is a very good test for finding CML cells. It can find "a needle in a haystack." Thus, it is the preferred testing method to see how treatment is working.

QPCR-IS scores

Across labs, different scales are used to measure and report QPCR test results. Thus, test results are not the same. It's like how money differs across countries. For example, $1 in the United States is not equal to €1 in Europe. Results can also differ within the same lab. To solve this problem, the IS (**I**nternational **S**cale) was made.

The IS score is the percentage of cells with *BCR-ABL1* that remain after treatment. **See Figure 9**. This is called the molecular response. A conversion factor is used to convert your results to the IS. It's like the exchange rate used to compare money from different countries. As a result, IS scores are consistent. Scores can also be compared between people and labs.

The IS uses a standard baseline of *BCR-ABL1* 100%. A tenfold drop from baseline is called a log reduction. A 1-log reduction (*BCR-ABL1* 10%) means there are 10 times fewer CML cells compared to baseline. A 2-log reduction (*BCR-ABL1* 1%) means 100 times fewer cells. A 3-log reduction (*BCR-ABL1* 0.1%) means 1,000 times fewer cells. A good lab can detect a 4.5-log reduction (*BCR-ABL1* 0.0032%).

Milestones

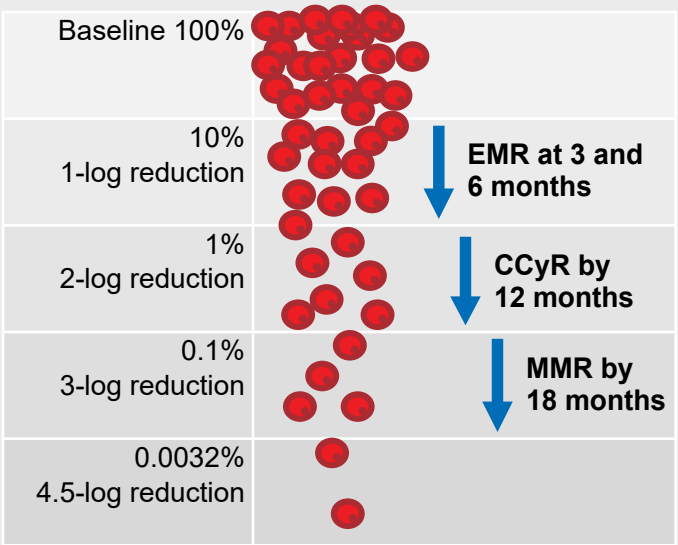
For CML, treatment results are discussed in terms of milestones. These milestones are:

- EMR (**e**arly **m**olecular **r**esponse) is defined as *BCR-ABL1* ≤10% at 3 months and 6 months. It is a sign of how well treatment will work long term.
- CCyR (**c**omplete **cy**togenetic **r**esponse) is the absence of the Philadelphia chromosome as measured by cytogenetics. A CCyR corresponds with *BCR-ABL1* 0.1% to *BCR-ABL1* 1%. It is often achieved within 12 months.
- MMR (**m**ajor **m**olecular **r**esponse) is defined as *BCR-ABL1* <0.1%. The goal is to reach this milestone between 12 and 18 months.

Although not a milestone, another treatment result is a CMR (**c**omplete **m**olecular **r**esponse). A CMR is when *BCR-ABL1* can't be detected. For this response, a lab that can detect at least a 4.5-log reduction is needed.

Figure 9
QPCR-IS scores and milestones

The IS score is the percentage of cells with *BCR-ABL1* that remain after treatment. Milestones are based on the percentage and time since treatment started.



Monitoring schedule

Guide 4 lists the schedule and tests advised by NCCN experts for monitoring. Green shows when milestones have been reached. Yellow shows when scores are of concern. Red shows scores failing milestones.

The first round of testing should occur 3 months after treatment. Monitoring includes a medical history, physical exam, CBC with differential, and QPCR-IS. Based on QPCR-IS results, other tests may be done.

Usual monitoring

When milestones are reached, usual monitoring is advised. You will receive a medical history, physical exam, CBC with differential, and QPCR-IS. It's also very important to keep taking your TKI. Your doctor will use the test results to plan how often monitoring is needed.

If your score stays low, continue monitoring every 3 months for at least 2 years. After 2 years, monitoring may be done every 3 to 6 months if your score is low enough.

After reaching MMR, your score may increase. If it increases by 1 log, QPCR-IS should be repeated in 1 to 3 months.

Medicine check & mutation testing

Certain scores at certain times will trigger more testing. These *BCR-ABL1* scores are greater than 10% at 6 months, 1% at 12 months, and 0.1% beyond 12 months. A 1-log increase after reaching *BCR-ABL1* <0.1% may also trigger more testing.

If these cases, your doctor may check if one of your medicines is limiting another. This is called drug interactions. Tell your doctor if you've been unable to take your medicine as prescribed. There may be ways to help you stay on track.

Mutation testing may also be done. After taking a TKI, CML cells may change so that the medicine doesn't work. These changes are called mutations. There are mutations known to limit TKIs. Mutation testing looks for these mutations.

Guide 4. Monitoring based on QPCR-IS

QPCR-IS BCR-ABL1 scores	3 months	6 months	12 months	Beyond 12 months
>10%	• Medicine check • Mutation testing	• Medicine check • Mutation testing • Cytogenetics	• Medicine check • Mutation testing • Cytogenetics	• Medicine check • Mutation testing • Cytogenetics
>1%–10%	• Usual monitoring	• Usual monitoring	• Medicine check • Mutation testing	• Medicine check • Mutation testing • Cytogenetics
0.1%–1.0%	• Usual monitoring	• Usual monitoring	• Usual monitoring	• Medicine check • Mutation testing
<0.1%	• Usual monitoring	• Usual monitoring	• Usual monitoring	• Usual monitoring

Cytogenetics
Bone marrow cytogenetics show if the Philadelphia chromosome is still present. It can also show other abnormal chromosomes. It is advised if BCR-ABL1 scores are greater than 10% at 6 months and 1% at 12 months. Cytogenetics may also be done if treatment seems to have stopped working (relapse).

Do not to stop or skip taking your medicine. Missing doses allows the leukemia cells to grow.

Second-line treatment

Guide 5 lists second-line treatment options based on QPCR-IS results. Green shows when milestones have been reached. Yellow shows when scores are of concern. Red shows scores failing milestones.

Milestones reached

When milestones are reached, stay on your TKI. It's very important not to stop or skip taking your medicine. Missing doses allows the leukemia cells to grow. Continue monitoring.

Stopping TKI

For certain people, stopping TKI treatment may be an option. Talk to your doctor if this is an option for you. You must meet certain conditions. These conditions include taking a TKI for 3 or more years. Your scores

Guide 5. Second-line treatment based on QPCR-IS

QPCR-IS BCR-ABL1 scores	3 months	6 months	12 months	Beyond 12 months
>10%	• Switch to new TKI • Same dose of nilotinib or dasatinib • Raise imatinib dose • Discuss HCT	• Switch to new TKI • Discuss HCT	• Switch to new TKI • Discuss HCT	• Switch to new TKI • Discuss HCT
>1%–10%	• Stay on TKI	• Stay on TKI	• Switch to new TKI • Same dose of nilotinib or dasatinib • Raise imatinib dose • Discuss HCT	• Switch to new TKI • Discuss HCT
0.1%–1.0%	• Stay on TKI	• Stay on TKI	• Stay on TKI	• Switch to new TKI • Same dose of nilotinib or dasatinib • Raise imatinib dose • Discuss HCT
<0.1%	• Stay on TKI	• Stay on TKI	• Stay on TKI	• Stay on TKI

HCT = hemopoietic cell transplant; TKI: tyrosine kinase inhibitor

must have remained at ≤0.01% for 2 or more years. There must be no history of TKI resistance.

If you stop, frequent monitoring is needed. This is to make sure your scores stay low. If scores increase, you will be able to start treatment early. Please note that most people who stop a TKI will relapse.

Scores of concern

The following scores are of concern: >10% at 3 months, >1% to 10% at 12 months, and 0.1% to 1.0% past 12 months. You may have four options.

One option is to switch to another TKI. Dasatinib, nilotinib, and bosutinib may work when imatinib does not. Bosutinib may work when dasatinib and nilotinib do not. Ponatinib may work when a *T315I* mutation is present. It may also work when other TKIs do not.

Another option may be to stay on the same dose of nilotinib or dasatinib. Your scores may reach milestones when tested next.

A third option may be to increase the dose if on imatinib. Of importance, side effects can worsen with higher doses. A higher dose is not likely to be helpful if the standard dose didn't help.

The fourth option is to discuss if allogeneic HCT is right for you. You may talk with a transplant expert. HLA typing may be done.

Scores failing milestones

If milestones are not met or maintained, you may have two options. One option is to switch to another TKI. The other option is to discuss if HCT is right for you. You may talk with a transplant expert.

Review

- Your doctor will plan your treatment based on many factors.
- First-line treatment options include imatinib, dasatinib or nilotinib, and a clinical trial.
- After starting treatment, testing on a regular basis is needed to check treatment results.
- Second-line treatment options include switching your TKI, staying on your TKI, higher-dose imatinib, and allogeneic HCT.

5
Treatment guide: Advanced phases

CML is most often diagnosed in the chronic phase. However, it can progress to the accelerated phase or blast phase. Treatment is less standardized for these advanced phases because they are less common. Doctors agree that the best chance of a cure is with an HCT. In Part 5, diagnosis and treatment of advanced phases are explained.

Additional testing

In Part 2, tests needed to plan CML treatment were described. For advanced phases, a few more tests are required. Some of these tests will reveal more about the CML you have. Other tests are needed for certain treatments.

Flow cytometry

Flow cytometry is a method used to assess surface proteins on cells. It is performed on either blood or bone marrow. First, a marker—a light-sensitive dye—will be added to the sample. Then, your blood will be passed through a flow cytometry machine. The machine measures surface proteins on thousands of cells.

Flow cytometry is used to find out the type of cells present. It'll show if the leukemia cells are mostly myeloid cells or lymphoid cells. This test is important because the cell type may affect which treatment is best for you.

Mutation testing

New mutations in the *BCR-ABL1* gene may occur over time. They can happen as CML progresses to advanced phases. They can also happen during treatment for CML.

Mutation testing is used to assess for these new mutations. Testing can be performed on blood or bone marrow. It should be done prior to starting treatment for advanced phase CML.

HLA testing

Not everyone can receive an allogeneic HCT. It can be hard on the body. Your doctor will assess if it is an option for you. If it is, testing will be needed.

HLAs (**h**uman **l**eukocyte **a**ntigens) are proteins found on the surface of most cells. They are markers of your body's cells. They allow your body to tell which cells are its own and which are foreign.

HLAs do not differ between cells within a person. In other words, all your cells have the same set of HLAs. Each person's set of HLAs is called the HLA type or tissue type.

HLA typing is a test that detects a person's HLA type. You will receive this test if HCT may be a treatment option.

HLA typing is needed to find the right donor for you. A donor's HLA type must be a near-perfect match to you for treatment to work. Otherwise, your body will reject the donor's stem cells.

Lumbar puncture

CML in the blast phase can spread into the fluid around the brain and spinal cord. This fluid is called cerebrospinal fluid or spinal fluid. To confirm that CML is in spinal fluid, a sample must be removed and tested.

A lumbar puncture is a procedure that removes spinal fluid. It is also called a spinal tap. It is advised for blast phase CML if mostly lymphoid cells are present.

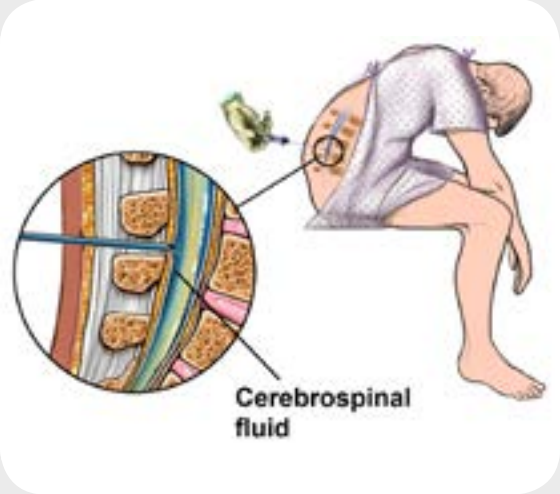
During a spinal tap, you will be lying down or sitting on an exam table. If lying down, your knees must

be tucked up near your chest. If sitting, you must lean slightly forward and down toward your knees as shown in **Figure 10**.

The lower part of your back over your spine will be numbed with a local anesthetic. Next, a thin needle will be inserted between the bones of your spine and into the space around your spinal cord. You may feel some pressure during the procedure. The fluid sample will then be sent to a lab for testing.

Figure 10
Lumbar puncture

A lumbar puncture is used to remove a sample of spinal fluid so it can be tested for cancer. A lumbar puncture may also be used to inject cancer drugs into spinal fluid.



Treatment

Your doctor will plan your treatment based on many factors. These factors include your age and health history. Results of tests and any prior TKI treatment will also be used for planning.

Accelerated phase

Guide 6 lists three options for accelerated phase. The treatment goal is to stop the leukemia from progressing to blast phase. For long-term control, an HCT is needed.

Clinical trial

One option is to join a clinical trial. A clinical trial is a type of research that studies how safe and helpful a treatment is. Trials that assess TKIs with chemotherapy or other treatments are advised. Think about joining a clinical trial on treatment for a *T315I* mutation.

TKI

The second option is treatment with a TKI. If you were treated for chronic phase, don't use the same TKI. If diagnosed in accelerated phase, your first treatment can be imatinib, dasatinib, or nilotinib. Treatment may also be chosen based on mutational testing results. If the TKI works, HCT is advised to keep CML in remission.

Omacetaxine

The third option is to receive omacetaxine. It is a chemotherapy agent. It is an option if CML progresses during two or more TKI treatments. It is also option if a *T315I* mutation is present.

Treatment results

While on treatment, testing to assess the results is needed. Tests will include a medical history, physical exam, CBC with differential, and QPCR-IS. In due time, an HCT is needed. If the leukemia worsens, read the next section for treatment of blast phase.

Guide 6. Treatment for accelerated phase

What are the options?
• Clinical trial
• TKI
◦ Imatinib if not received before
◦ Dasatinib if *Y253H*, *E255K/V*, or *F359V/C/I* mutations
◦ Nilotinib if *F317L/V/I/C*, *T315A*, or *V299L* mutations
◦ Bosutinib if *E255K/V*, *F317L/V/I/C*, *F359V/C/I*, *T315A*, or *Y253H* mutations
◦ Ponatinib if *T315I* mutation or no other TKI option
• Omacetaxine if *T315I* mutation or leukemia worsens on 2 or more TKIs

Blast phase

CML in the blast phase can act like an acute leukemia. Acute leukemias include ALL and AML. Your treatment will be based on whether the leukemia cells are mostly lymphoid or myeloid.

Guide 7 lists the options for blast phase. Options are based on the main cell type. For long-term control, an HCT is needed.

Clinical trial

One option is to join a clinical trial. A clinical trial is a type of research that studies how safe and helpful a treatment is. Trials for advanced phases are advised in general. Recent trials are assessing TKIs with chemotherapy or other treatments. There may be a clinical trial on treatment for a *T315I* mutation.

TKI

The second option is treatment with a TKI. If you were treated for chronic phase, don't use the same TKI. If diagnosed in accelerated phase, your first treatment can be imatinib, dasatinib, or nilotinib. Treatment may also be chosen based on mutational testing results. If the TKI works, HCT is advised to keep CML in remission.

Guide 7. Treatment for blast phase

Main cell type	What are the options?
Lymphoid	• Clinical trial
	• TKI + ALL-type chemotherapy
	◦ Imatinib if not received before
	◦ Dasatinib if *Y253H*, *E255K/V*, or *F359V/C/I* mutations
	◦ Nilotinib if *F317L/V/I/C*, *T315A*, or *V299L* mutations
	◦ Bosutinib if *E255K/V*, *F317L/V/I/C*, *F359V/C/I*, *T315A*, or *Y253H* mutations
	◦ Ponatinib if *T315I* mutation or no other TKI option
	• TKI + steroid
Myeloid	• Clinical trial
	• TKI + AML-type chemotherapy
	◦ Imatinib if not received before
	◦ Dasatinib if *Y253H*, *E255K/V*, or *F359V/C/I* mutations
	◦ Nilotinib if *F317L/V/I/C*, *T315A*, or *V299L* mutations
	◦ Bosutinib if *E255K/V*, *F317L/V/I/C*, *F359V/C/I*, *T315A*, or *Y253H* mutations
	◦ Ponatinib if *T315I* mutation or no other TKI option
	• TKI alone

Chemotherapy
Chemotherapy may be added to TKI treatment. The type of chemotherapy you will have depends on the main cell type. If lymphoid type, you will have chemotherapy that is used for ALL. If myeloid type, you will have chemotherapy that is used for AML.

Steroid
Steroid is the short name for corticosteroid. It is a type of drug that is often used to relieve inflammation. Steroids also are toxic to lymphoid cells. Thus, a steroid may be added to TKI treatment for lymphoid type.

CNS treatment
Sometimes CML involves or relapses in the CNS (**c**entral **n**ervous **s**ystem). In this case, special treatment is needed. CNS treatment may include chemotherapy injected into spinal fluid. This chemotherapy includes methotrexate, cytarabine, and steroids. CNS treatment may also be chemotherapy injected into a vein. This chemotherapy includes high-dose methotrexate, intermediate or high-dose cytarabine, mercaptopurine, and pegaspargase.

Allogeneic HCT
Allogeneic HCT is used after remission of blast-phase CML. It is the preferred treatment option. It may also be an option if *T315I* and other mutations cause TKIs not to work.

Treatment results
After a transplant, testing to assess the results is needed. Tests will include a medical history, physical exam, CBC with differential, and QPRC-IS. In due time, an HCT is needed. If the leukemia worsens, you may receive another treatment listed in Guide 7.

HCT follow-up treatment

Your doctor will assess if the allogeneic HCT worked. Signs that it did work include QPCR-IS results of *BCR-ABL1* 0.1% to *BCR-ABL1* 1%. An absence of the Philadelphia chromosome as measured by cytogenetics is another sign.

Guide 8 lists options for the next steps of care. If HCT worked, results will be monitored with QPCR-IS. Testing will occur every 3 months for 2 years. If results stay normal, testing will then occur every 3 to 6 months thereafter. Taking a TKI for 1 year after HCT may improve results and prevent relapse.

If HCT didn't work or you have a relapse, talk with your transplant doctor about options. Options will depend on your prior treatment, mutations, and health. One option may be a TKI. Getting a DLI (**d**onor **l**ymphocyte **i**nfusion) with TKI may cause a fast drop in *BCR-ABL1*. DLI consists of receiving lymphocytes from the same person who donated the blood stem cells for the HCT.

A third option may be omacetaxine. It is given when two or more TKIs didn't work. The fourth option is to receive treatment within a clinical trial.

Guide 8. Treatment after HCT

Test results	What are the options?
Transplant worked	• Think about taking TKI for 1 year
Transplant did not work or the leukemia has worsened after successful transplant	• TKI
	• TKI + DLI
	• Omacetaxine
	• Clinical trial

Review

- Additional testing is needed for advanced phases to plan the best treatment.
- Treatment options are based on prior treatment, mutations in CML cells, and your health. Joining a clinical trial is encouraged.
- TKIs are often used to treat the advanced phase. Chemotherapy or steroids may be added if in blast phase.
- Some people may receive an allogeneic HCT. If there is a big drop in CML cells, think about taking a TKI for 1 year. If CML cells remain high or increase, talk with your transplant doctor about treatment options.

6
Making treatment decisions

Having cancer is very stressful. While absorbing the fact that you have cancer, you have to learn about tests and treatments. In addition, the time you have to accept a treatment plan feels short. Parts 1 through 5 described the cancer and treatment options. Part 6 aims to help you make decisions that are in line with your beliefs, wishes, and values.

It's your choice

The role each person wants in choosing his or her treatment differs. You may feel uneasy about making treatment decisions. This may be due to a high level of stress. It may be hard to hear or know what others are saying. Stress, pain, and drugs can limit your ability to make good decisions. You may feel uneasy because you don't know much about cancer. You've never heard the words used to describe cancer, tests, or treatments. Likewise, you may think that your judgment isn't any better than your doctors'.

Letting others decide which option is best may make you feel more at ease. But, whom do you want to make the decisions? You may rely on your doctors alone to make the right decisions. However, your doctors may not tell you which option to choose if you have multiple good options. You can also have loved ones help. They can gather information, speak on your behalf, and share in decision-making with your doctors. Even if others decide which treatment you will receive, you still have to agree by signing a consent form.

On the other hand, you may want to take the lead or share in decision-making. Most patients do. In shared decision-making, you and your doctors share information, weigh the options, and agree on a treatment plan. Your doctors know the science behind your plan but you know your concerns and goals. By working together, you are likely to get a higher quality of care and be more satisfied. You'll likely get the treatment you want, at the place you want, and by the doctors you want.

Questions to ask your doctors

You may meet with experts from different fields of medicine. Strive to have helpful talks with each person. Prepare questions before your visit and ask questions if the person isn't clear. You can also take notes and get copies of your medical records.

It may be helpful to have your spouse, partner, family member, or a friend with you at these visits. A patient advocate or navigator might also be able to come. They can help to ask questions and remember what was said. Suggested questions to ask are listed on the following pages.

What's my diagnosis and prognosis?

It's important to know that there are different types of cancer. Cancer can greatly differ even when people have a tumor in the same organ. Based on your test results, your doctor can tell you which type of cancer you have. He or she can also give a prognosis. A prognosis is a prediction of the pattern and outcome of a disease. Knowing the prognosis may affect what you decide about treatment.

1. Where did the cancer start? In what type of cell? Is this cancer common?
2. What is the CML phase? Does this phase mean the leukemia is advanced?
3. Is this a fast- or slow-growing leukemia?
4. What tests do you recommend for me?
5. Where will the tests take place? How long will the tests take and will any test hurt?
6. What if I am pregnant?
7. How do I prepare for testing?
8. Should I bring a list of my medications?
9. Should I bring someone with me?
10. How often are these tests wrong?
11. Would you give me a copy of the pathology report and other test results?
12. Who will talk with me about the next steps? When?

What are my options?

There is no single treatment practice that is best for all people. There is often more than one treatment option along with clinical trial options. Your doctor will review your test results and recommend treatment options.

1. What will happen if I do nothing?
2. Can I just carefully monitor the leukemia?
3. Do you consult NCCN recommendations when considering options?
4. Are you suggesting options other than what NCCN recommends? If yes, why?
5. Do your suggested options include clinical trials? Please explain why.
6. How do my age, health, and other factors affect my options? What if I am pregnant?
7. Which option is proven to work best?
8. Which options lack scientific proof?
9. What are the benefits of each option? Does any option offer a cure or long-term cancer control? Are my chances any better for one option than another? Less time-consuming? Less expensive?
10. What are the risks of each option? What are possible complications? What are the rare and common side effects? Short-lived and long-lasting side effects? Serious or mild side effects? Other risks?
11. How do you know if treatment is working?
12. What are my options if my treatment stops working?
13. What can be done to prevent or relieve the side effects of treatment?

What does each option require of me?

Many patients consider how each option will practically affect their lives. This information may be important because you have family, jobs, and other duties to take care of. You also may be concerned about getting the help you need. If you have more than one option, choosing the option that is the least taxing may be important to you:

1. Will I have to go to the hospital or elsewhere? How often? How long is each visit?
2. What do I need to think about if I will travel for treatment?
3. Do I have a choice of when to begin treatment? Can I choose the days and times of treatment?
4. How do I prepare for treatment? Do I have to stop taking any of my medicines? Are there foods I will have to avoid?
5. Should I bring someone with me when I get treated?
6. Will the treatment hurt?
7. How much will the treatment cost me? What does my insurance cover?
8. Will I miss work or school? Will I be able to drive?
9. Is home care after treatment needed? If yes, what type?
10. How soon will I be able to manage my own health?
11. When will I be able to return to my normal activities?

What is your experience?

More and more research is finding that patients treated by more experienced doctors have better results. It is important to learn if a doctor is an expert in the cancer treatment he or she is offering.

1. Are you board-certified? If yes, in what area?
2. How many patients like me have you treated?
3. How many procedures like the one you're suggesting have you done?
4. Is this treatment a major part of your practice?
5. How many of your patients have had complications?

Deciding between options

Deciding which option is best can be hard. Doctors from different fields of medicine may have different opinions on which option is best for you. This can be very confusing. Your spouse or partner may disagree with which option you want. This can be stressful. In some cases, one option hasn't been shown to work better than another. Some ways to decide on treatment are discussed next.

2nd opinion

The time around deciding a treatment is very stressful. People with cancer often want to get treated as soon as possible. They want to make their cancer go away before it spreads farther. While cancer can't be ignored, usually there is time to think about and choose which option is best for you.

You may wish to have another doctor review your test results and suggest a treatment plan. This is called getting a 2nd opinion. You may completely trust your doctor, but a 2nd opinion about which option is best can help.

Copies of the pathology report, a DVD of the imaging tests, and other test results need to be sent to the doctor giving the 2nd opinion. Some people feel uneasy asking for copies from their doctors. However, a 2nd opinion is a normal part of cancer care.

When doctors have cancer, most will talk with more than one doctor before choosing their treatment. What's more, some health plans require a 2nd opinion. If your health plan doesn't cover the cost of a 2nd opinion, you have the choice of paying for it yourself.

If the two opinions are the same, you may feel more at peace about the treatment you accept to have. If the two opinions differ, think about getting a 3rd opinion. A 3rd opinion may help you decide between your options. Choosing your cancer treatment is a very important decision. It can affect your length and quality of life.

Support groups

Besides talking to health experts, it may help to talk to other people who have walked in your shoes. At support groups, you can ask questions and hear about the experiences of other people with leukemia. Find a support group at the websites listed on page 47.

Compare benefits and downsides

Every option has benefits and downsides. Consider these when deciding which option is best for you. Talking to others can help identify benefits and downsides you haven't thought of. Scoring each factor from 0 to 10 can also help since some factors may be more important to you than others.

Websites

Leukemia & Lymphoma Society
LLS.org/informationspecialists

National Cancer Institute (NCI)
cancer.gov/types/types/leukemia/patient/cml-treatment-pdq

National Coalition for Cancer Survivorship
canceradvocacy.org/toolbox

NCCN for Patients®
nccn.org/patients

Review

- Shared decision-making is a process in which you and your doctors plan treatment together.
- Asking your doctors questions is vital to getting the information you need to make informed decisions.
- Getting a 2nd opinion, attending support groups, and comparing benefits and downsides may help you decide which treatment is best for you.

Glossary

Dictionary

accelerated phase
The second phase of chronic myelogenous leukemia progression, when the number of blast cells is increased.

acute lymphoblastic leukemia (ALL)
A fast-growing cancer that causes too many immature white blood cells called lymphoblasts to be made.

acute myeloid leukemia (AML)
A fast-growing cancer that causes too many immature white blood cells called myeloblasts to be made.

adherence
The extent to which you take your medicine the right way, as explained by your doctor.

advanced phase
A rating of chronic myelogenous leukemia, when the number of immature blood cells (blast cells) is high and it is causing symptoms.

allogeneic hematopoietic cell transplant (HCT)
A treatment in which the patient receives healthy, immature blood-forming cells from another person to replace damaged or diseased cells in the bone marrow. Also called allogeneic stem cell transplant.

anemia
A health condition in which the number of red blood cells is low.

basophil
A type of white blood cell that helps fight infections and has small particles (granules).

***BCR-ABL1* gene**
An abnormal gene that is formed when the *BCR* gene and *ABL* gene join together on the Philadelphia chromosome. Also called *BCR-ABL1* fusion gene.

BCR-ABL1 protein
An abnormal protein that is made by the *BCR-ABL1* fusion gene and causes too many abnormal white blood cells to be made.

blast cell
An immature blood cell.

blast phase
The final phase of chronic myelogenous leukemia, which has the highest number of blast cells in the blood and bone marrow and can be life-threatening. Also called blast crisis.

blood chemistry profile
A test that measures the amounts of many different chemicals in a sample of blood.

blood stem cell
An immature blood-forming cell from which all other types of blood cells are made. Also called hematopoietic stem cell.

bone marrow
The soft, sponge-like tissue in the center of most bones where blood cells are made.

bone marrow aspiration
The removal of a small amount of liquid bone marrow to test for disease.

bone marrow biopsy
The removal of a small amount of solid bone and bone marrow to test for disease.

bone marrow cytogenetics
Test of a sample of bone marrow to look for changes in the cells' chromosomes.

chemotherapy (chemo)
Drugs that kill fast-growing cells, including cancer cells and normal cells.

chromosomes
Long strands that contain bundles of coded instructions in cells for making and controlling cells.

chronic myelogenous leukemia (CML)
A slow-growing cancer that starts in the bone marrow and causes too many granulocytes to form.

chronic phase
The first phase of chronic myelogenous leukemia, when the number of white blood cells is higher than normal but may not cause symptoms.

clinical trial
Research on a test or treatment to assess its safety or how well it works.

complete blood count (CBC)
A test of the number of blood cells.

complete blood count (CBC) with differential
A test of the number of blood cells as well as the different types of white blood cells in a sample.

complete cytogenetic response (CCyR)
When tests don't find any copies of the Philadelphia chromosome.

complete molecular response (CMR)
No copies of the abnormal *BCR-ABL1* gene are found using a very sensitive test.

cytogenetics
The study of chromosomes.

deoxyribonucleic acid (DNA)
A chain of chemicals in cells that contains genes and is bundled into long strands called chromosomes.

diagnose
To confirm or identify a disease or health condition.

donor
A person who gives his/her organs, tissues, or cells to another person.

donor lymphocyte infusion (DLI)
Procedure in which the patient receives white blood cells from the same person who donated blood-forming cells for the stem cell transplant.

drug interaction
A change in the way a drug acts or works in the body when it is taken with another drug or substance.

drug resistance
When cancer does not respond to a drug treatment.

eosinophil
A type of white blood cell that helps fight infections and has small particles (granules).

fatigue
Severe tiredness despite getting enough sleep that limits one's ability to function.

flow cytometry
A test that looks at certain substances on the surface of cells to identify the type of cells present.

fluorescence in situ hybridization (FISH)
A lab test that uses special dyes to look for abnormal changes in a cell's genes.

fusion gene
A gene that is made when parts of two separate genes join together.

gene
A set of coded instructions in cells for making new cells and controlling how cells behave.

graft-versus-host disease (GVHD)
A disease that occurs when transplanted blood stem cells attack a patient's normal cells.

graft-versus-leukemia (GVL) effect
An attack on cancer cells by transplanted blood stem cells.

granulocyte
A type of white blood cell that has small particles (granules).

hematologist
A doctor who's an expert in diseases of the blood.

hematopoietic cell
An immature blood-forming cell from which all other types of blood cells are made. Also called blood stem cell.

hematopoietic cell transplant (HCT)
A treatment that replaces damaged or diseased cells in the bone marrow with healthy blood-forming cells. Also called stem cell transplant.

human leukocyte antigen (HLA)
Special proteins on the surface of cells that help the body to tell its own cells apart from foreign cells.

human leukocyte antigen (HLA) testing
A blood test that finds a person's HLA type—the unique set of proteins on the surface of cells that helps the body to tell its own cells apart from foreign cells.

human leukocyte antigen (HLA) type
The unique set of proteins on the surface of cells that helps the body to tell its own cells apart from foreign cells.

immune system
The body's natural defense against infection and disease.

International Scale (IS)
A standardized scale for measuring and reporting results of a very sensitive test that measures the number of cells that have the *BCR-ABL1* gene.

intolerance
When treatment with a drug must be stopped due to severe side effects.

liver
An organ that removes waste from the blood and helps to digest food.

log reduction
A decrease in the number of cells that have the *BCR-ABL1* gene.

lymphocyte
A type of white blood cell that helps protect the body from infection and disease.

lymphoid
Referring to a type of white blood cell called a lymphocyte.

major molecular response (MMR)
An improvement related to treatment, when tests detect a 3-log reduction in *BCR-ABL1* levels. It means that there are 1,000 times fewer cells with the *BCR-ABL1* gene than the standardized baseline level.

medical history
All health events and medications taken to date.

molecular response
An improvement related to treatment, when tests detect a decrease in the number of cells that have the *BCR-ABL1* gene.

mutation
An abnormal change in the coded instructions in cells for making and controlling cells.

mutation testing
A test that looks for abnormal changes in genes (the coded instructions in cells for making and controlling cells).

myeloid
Referring to a type of white blood cell called a granulocyte.

neutrophil
A type of white blood cell that helps fight infections and has small particles (granules).

pathologist
A doctor who's an expert in testing cells and tissue to find disease.

Philadelphia chromosome
An abnormal, short chromosome 22 that is formed when parts of chromosomes 9 and 22 switch with each other. It is the hallmark of chronic myelogenous leukemia and contains the *BCR-ABL1* gene.

physical exam
A review of the body by a health expert for signs of disease.

prognosis
The likely or expected course and outcome of a disease.

quantitative reverse transcriptase polymerase chain reaction (QPCR)
A very sensitive test that measures the number of cells in the blood or bone marrow that have the *BCR-ABL1* gene.

relapse
The return or worsening of cancer after a period of improvement.

remission
There are minor or no signs of a disease.

resistance
When cancer does not respond to a drug treatment.

risk group
Grouping of patients who will likely have a similar treatment outcome.

secondary resistance
When cancer responds to a drug at first, but then stops responding after a period of time.

second-line treatment
The next treatment used against a disease after the first treatment failed or had to be stopped.

sedative
A drug that helps a person to relax or go to sleep.

side effect
An unhealthy or unpleasant physical or emotional condition caused by treatment.

spleen
An organ to the left of the stomach that helps protect the body from disease.

steroid
A drug used to reduce swelling, pain, and redness.

supportive care
Treatment for the symptoms or health conditions caused by cancer or cancer treatment.

symptom
A new or changed health problem a person experiences that may indicate a disease.

targeted therapy
Treatment with drugs that target a specific or unique feature of cancer cells.

transfusion
Replacing lost blood with new blood.

translocation
When pieces of two chromosomes (long strands of coded instructions for controlling cells) break off and switch with each other.

treatment response
An outcome or improvement in disease that is caused by treatment.

tyrosine kinase
A type of protein in cells that sends signals that tell cells when to grow and divide to make new cells.

tyrosine kinase inhibitor (TKI)
A type of drug that attaches to the BCR-ABL1 protein so that it can’t send growth signals.

white blood cell
A type of blood cell that helps fight infections in the body.

Acronyms

ALL
acute lymphoblastic leukemia

AML
acute myeloid leukemia

CAM
complementary and alternative medicine

CBC
complete blood count

CCyR
complete cytogenetic response

CBC
complete blood count

CML
chronic myeloid leukemia

CMR
complete molecular response

DLI
donor lymphocyte infusion

DNA
deoxyribonucleic acid

EMR
early molecular response

FDA
Food and Drug Administration

FISH
fluorescence in situ hybridization

GVL
graft-versus-leukemia

HCT
hematopoietic cell transplant

HLA
human leukocyte antigen

IS
International Scale

NCCN
National Comprehensive Cancer Network

MMR
major molecular response

MPN
myeloproliferative neoplasm

QPCR
quantitative reverse transcriptase-polymerase chain reaction

TKI
tyrosine kinase inhibitor

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507.538.3270 • Minnesota
mayoclinic.org/departments-centers/mayo-clinic-cancer-center

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mskcc.org

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Tampa, Florida
800.456.3434
moffitt.org

The Ohio State University Comprehensive Cancer Center - James Cancer Hospital and Solove Research Institute
Columbus, Ohio
800.293.5066
cancer.osu.edu

Roswell Park Cancer Institute
Buffalo, New York
877.275.7724
roswellpark.org

Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine
St. Louis, Missouri
800.600.3606
siteman.wustl.edu

St. Jude Children's Research Hospital
The University of Tennessee Health Science Center
Memphis, Tennessee
888.226.4343 • stjude.org
901.683.0055 • westclinic.com

Stanford Cancer Institute
Stanford, California
877.668.7535
cancer.stanford.edu

University of Alabama at Birmingham Comprehensive Cancer Center
Birmingham, Alabama
800.822.0933
www3.ccc.uab.edu

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La Jolla, California
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Ann Arbor, Michigan
800.865.1125
mcancer.org

The University of Texas MD Anderson Cancer Center
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mdanderson.org

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uwhealth.org/cancer

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800.811.8480
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Chronic Myeloid Leukemia

2018

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PAT-N-1018-1017