



**The Leukemia &
Lymphoma Society®**
Fighting Blood Cancers

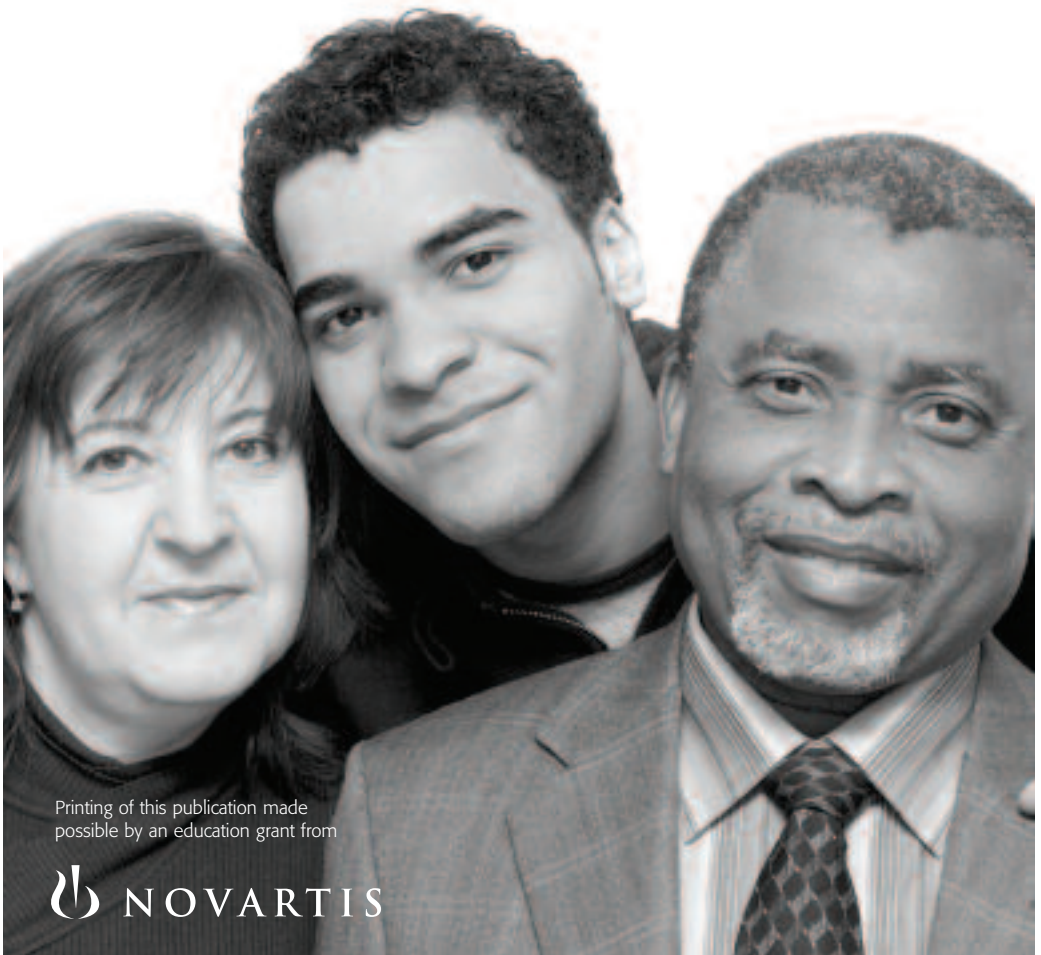
CML: A Guide for Patients and Caregivers

CHRONIC MYELOGENOUS LEUKEMIA

LEUKEMIA

LYMPHOMA

MYELOMA



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 **NOVARTIS**

Introduction

About 4,500 Americans learn they have chronic myelogenous leukemia (CML) each year.

Children and adults can get CML at any age, but most CML patients are adults.

This booklet is for patients with CML, their families and caregivers. It will help them learn about CML and how it is treated. The progress that has been made in treating CML gives patients more hope than ever before.

Part 1 discusses:

- What is CML?
- Who gets CML?
- How does the doctor find CML?

Part 2 discusses:

- What is the treatment for CML?
- What are the side effects of the treatment?
- How do I get more information?

This booklet about CML is from The Leukemia & Lymphoma Society. It is for information only. The Society does not give medical advice or medical services.

1 **Questions? Contact an Information Specialist at The Leukemia & Lymphoma Society at www.LLS.org or (800) 955-4572.**

Inside This Booklet

Part 1 - Understanding	
Chronic Myelogenous Leukemia	3
Signs and Symptoms	6
Blood and Bone Marrow Tests	8
Phases of CML	10
Part 2 - Treatment	
Chronic Phase Treatment – Drug Therapy	11
Accelerated Phase or Blast Crisis Phase Treatment	14
Related Disorders	22
Clinical Trials	22
Talking to the Doctor	25
Coping with CML	27
Medical Terms	33
We're Here to Help	38

Some words in the booklet may be new to you. Check “Medical Terms” at the back of this booklet.

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2

Part 1 – Understanding Chronic Myelogenous Leukemia

Leukemia is a type of cancer. There are 4 main types of leukemia. Chronic myelogenous leukemia (CML) is 1 of the 4 types.

CML starts with a change to a single stem cell. A stem cell is a type of cell found in marrow that makes red cells, white cells and platelets.

Every cell with a nucleus has **chromosomes** that carry genes. Genes give instructions to cells. Normal cells have pairs of chromosomes numbered 1–22. Also, females have two “X chromosomes.” Males have one “X” and one “Y” chromosome.

CML patients have what is called the “**Philadelphia chromosome**” (**Ph chromosome**). The Ph chromosome is made as a result of a piece of chromosome 22 breaking off.

3 Check **Medical Terms** for words that are new to you.
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With CML, there is a switch in pieces of chromosome 9 and 22. A switch between parts of chromosomes is called a **translocation**.

The break on chromosome 9 involves a gene called **ABL**. The break on chromosome 22 involves a gene called **BCR**.

A piece of chromosome 9 attaches to the end of chromosome 22 and the **BCR-ABL cancer gene** is made.

Genes give cells instructions for making proteins. Proteins help the cell to do its job. The protein made by the BCR-ABL gene gives instructions that lead to CML.

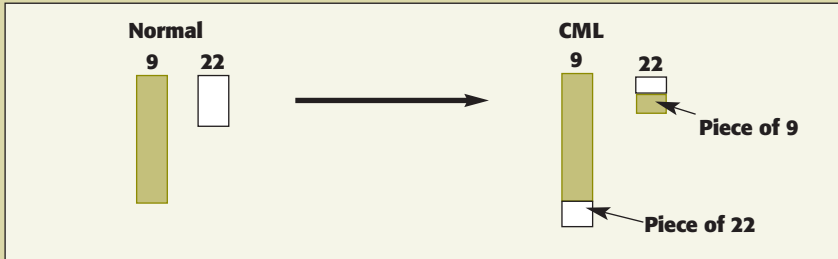
Drug treatments that target the BCR-ABL gene are described starting on page 11.



For more details on the disease and its treatment order The Leukemia & Lymphoma Society's free booklet, *Chronic Myelogenous Leukemia*.

To order free booklets, contact **The Leukemia & Lymphoma Society** at **www.LLS.org** or **(800) 955-4572**.

How Is the BCR-ABL Cancer Gene Made?



- A piece of the ABL gene from chromosome 9 breaks off.
- A piece of the BCR gene on chromosome 22 breaks off.
- These 2 pieces switch places. The switch leads to the cancer gene called BCR-ABL.

Doctors are working to understand the changes that lead to the Ph chromosome and the BCR-ABL cancer gene.

Some things that may cause these changes are:

- Very high levels of radiation (such as atomic bomb survivors were exposed to in World War II)
- High-dose radiation therapy used to treat other cancers

There is no link between dental or medical x-rays and increased risk of CML. You cannot catch CML from someone else.

Signs and Symptoms

CML signs and symptoms tend to develop slowly. Some patients learn about their CML after a routine blood test given during a check-up.

A sign is a change in the body that the doctor sees in an exam or a lab test. A symptom is a change in the body that a patient can see or feel.

Some changes that a person with **CML** may have are:

- Tiredness
- Shortness of breath doing activities
- Pale-looking skin
- Swelling of the spleen (on the upper left side of the belly)
- Night sweats
- Weight loss

These signs and symptoms for CML are common to other illnesses.

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About Marrow, Blood and Blood Cells

Marrow is the spongy center inside of bones.

Blood cells are made in the marrow. Blood cells begin as stem cells. Stem cells become either red cells, white cells or platelets in the marrow. Then the red cells, white cells and platelets enter the blood.

Plasma is also part of the blood. It is mostly water. It also has some vitamins, minerals, proteins, hormones and other natural chemicals.

Platelets prevent bleeding and form plugs that help stop bleeding after an injury.

Red cells carry oxygen around the body. When the number of red cells is below normal this is called anemia. Anemia can make you tired, pale or short of breath.

White cells fight infection in the body. A neutrophil is one type of white cell that fights infection.

Blood and Bone Marrow Tests

Blood and bone marrow tests are done to look for leukemia cells to find out if a person has CML. In CML, the white cell count increases, often to very high levels. Platelet counts may also be high. Levels of **hemoglobin**, the substance in red blood cells that carries oxygen, go down.

A CML diagnosis is usually clear from an exam of blood cells. A **bone marrow aspirate** and a **bone marrow biopsy** are two tests that are done to look at the marrow cells for changes that can't be seen in blood cells. These tests may be done in the doctor's office or in a hospital. The two tests are almost always done together. They may help the doctor choose the best treatment for the patient. These tests also help the doctor to follow the effects of therapy.

With a **bone marrow aspiration**, first, the patient gets medication to numb the skin. Then, a special needle is inserted through the patient's hip bone into the marrow. **A sample of cells** is removed. The cells are viewed under a microscope to identify abnormal cells. The sample of cells can also be used for **cytogenetic analysis, PCR** and other tests.

Check **Medical Terms** for words that are new to you.
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A **bone marrow biopsy** is different from a marrow aspiration. First the patient gets medication to numb the skin. Then a special biopsy needle is used to remove a **core of bone containing marrow**. The marrow is examined under a microscope to see if there are abnormal cells.

Cytogenetic analysis is a lab test to examine the **chromosomes** of the leukemia cells. This test helps the doctor find out if the patient has CML.

FISH (fluorescence in situ hybridization) is a test that is used to measure the patient's remaining percent of CML cells.

PCR (polymerase chain reaction) is a very sensitive test that is used when there are no CML cells found by FISH.

These tests are used to diagnose CML. They are also used to check a patient's response to treatment.

It is important to get treatment in a center where doctors are experienced in the care of patients with CML. Some patients may want to get a second medical opinion to better understand their illness, treatment and follow-up.

Phases of CML

CML can have 3 phases:

- The chronic phase
- The accelerated phase
- The blast crisis phase

Most patients are in the **chronic phase** of the disease when their CML is found. During this phase, CML symptoms are less intense. White cells can still fight infection. Once patients in the chronic phase are treated, red cells and platelets can do their jobs. Most patients can go back to their usual activities.

In the **accelerated phase**, the patient may develop **anemia** (a decrease in the amount of red cells in the blood). The number of white cells may go up or down. The number of platelets may drop. The number of early bone marrow cells, called **blast cells**, increases. The spleen may swell and the patient may feel ill.

During the **blast crisis phase**, the number of blast cells grows in marrow and blood. The number of red cells and platelet cells drops. The patient may have bleeding and infections. The patient may be tired, have shortness of breath, stomach pain, bone pain or bleeding.

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10

Part 2 – Treatment

Chronic Phase Treatment – Drug Therapy

The goal in treating chronic phase CML is to bring:

- the level of blood cells back to normal and
- get rid of cells with the BCR-ABL cancer gene.

Drugs Used Most Often for Chronic Phase CML Treatment

Usual Initial Treatment

Imatinib mesylate (Gleevec®)

Other Treatments*

Dasatinib* (Sprycel®)

Nilotinib** (Tasigna®)

Hydroxyurea (Hydrea®)

Gleevec®, Sprycel® and Tasigna® are drugs that block the protein made by the BCR-ABL cancer gene. Patients who do not respond to these drugs may be treated with interferon or other drugs.

Hydrea® may be used to decrease white cell counts.

* This drug is usually for patients who do not respond well to Gleevec®

** This drug is under study

In chronic phase CML, treatment usually returns the level of blood cells to normal. The spleen shrinks toward normal size. Most patients don't have infections or unusual bleeding.

Patients with CML begin treatment with a drug called imatinib mesylate (Gleevec®). Gleevec® is a type of drug called a **BCR-ABL tyrosine kinase inhibitor**. It has been FDA approved since 2001. For some patients, Gleevec® keeps CML under control for as long as they take the drug.

Some patients taking Gleevec® have strong side effects or the drug does not work for them. Patients who do not respond to the usual dose of Gleevec® may do better with a higher dose.

For other patients, there are two newer drugs called dasatinib (Sprycel®) and nilotinib (Tasigna®). These drugs also block the BCR-ABL cancer gene. They work in a different way than Gleevec®.

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All 3 of these drugs are taken by mouth. Sprycel® is an FDA approved drug for certain CML patients who do not respond to Gleevec®. Tasigna® is available only to patients in clinical trials (as of the time this booklet was written). More information about clinical trials is on page 22.

Most patients being treated in the chronic phase of CML can go about their day-to-day activities. With drug treatment, most patients are symptom-free for very long periods (called a **remission**).

However, patients are not cured of CML with drug treatment. They are checked carefully for any signs that CML is returning (called a **relapse**). They will need regular health check-ups, including blood tests. From time to time a patient will need a bone marrow test.

CML is likely to return if drug treatment is stopped. The disease may also return if the drug stops working. There are other treatments for these patients.

Accelerated Phase or Blast Crisis Phase Treatment

The goal in treating **accelerated** or **blast crisis phase CML** is to kill all cells that contain the BCR-ABL gene or to return the patient's disease to the chronic phase.

Gleevec[®], and for certain patients, Sprycel[®], are important treatments for accelerated or blast crisis phase patients. Stem cell transplantation is another important treatment for certain patients. Information about stem cell transplant begins on page 17.

Treatment Response

Measuring treatment response is very important. The doctor may use the terms **hematological**, **cytogenetic** or **molecular** remission (response).

Blood tests can be used to see if a patient has a complete **hematological response** (red cell, white cell and platelet counts are normal or near normal).

A blood test or a bone marrow biopsy may be used to do FISH and/or PCR testing.

FISH is used to measure the patient's **cytogenetic response** (the percent of CML cells that remain).

PCR is used to measure the patient's **molecular response** (the extent to which the BCR-ABL gene is decreased).

Most CML patients in chronic phase CML have a complete hematologic response with Gleevec®. Many of these patients go on to have a complete cytogenetic response. They may also have a partial or complete molecular response.

There are other treatments for patients who do not get a good response with Gleevec®.

Side Effects of Gleevec® and Sprycel® Treatment

Many treatment side effects go away or become less noticeable over time.

Gleevec® may cause some side effects. Most can be handled without the need to stop the drug.

These more common effects include:

- Swelling from too much fluid in the body
- Puffiness around the eyes
- Nausea
- Vomiting
- Muscle cramps
- Diarrhea
- Rash
- Bone and/or joint pain
- Too few white cells and/or platelets

Gleevec® may also cause loss of bone minerals. In rare cases, the drug may affect the heart. The doctor will check patients for these possible side effects.

Side effects of Sprycel® may include:

- Too few white cells and/or platelets
- Too much fluid in the chest
- Diarrhea
- Headache
- Low calcium levels in the blood
- Slight changes in liver function _____

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Doctors are studying how CML treatment affects pregnancy. They want to learn if Gleevec®, Sprycel® and other CML drugs cause miscarriage and/or birth defects. In the meantime, most doctors advise women in treatment for CML to use birth control. Speak to your doctor for more information.



The Society's free booklet, *Understanding Drug Therapy and Managing Side Effects*, has more information about drugs and side effects.

Stem Cell Transplant

A **stem cell transplant** (sometimes called a bone marrow transplant) is used for some patients with CML.

Donated stem cells (**allogeneic transplant**) or the patient's own stem cells (**autologous infusion**) are injected into the patient's blood after chemotherapy ends.

More information about allogeneic stem cell transplant follows. Information about autologous stem cell infusion begins on page 20.



The Society's free booklet, *Blood and Marrow Stem Cell Transplantation*, has more details on this topic.

Allogeneic Stem Cell Transplant

Stem cells from a donor are transfused into the patient's blood after chemotherapy ends. Sometimes the donor can be a brother or a sister. About 1 out of 4 brothers or sisters has stem cells that "match" the patient's. When there is no related donor, the donor can be an unrelated person with stem cells that "match" the patient's.

High-dose chemotherapy is given to patients before a stem cell transplant to get rid of CML cells in the body. **Chemotherapy** is treatment with drugs that kill or damage cancer cells.

The transplanted stem cells go from the patient's blood to the marrow. The cells start a new supply of red cells, white cells (including immune cells) and platelets.

The donated stem cells make immune cells that are not totally "matched" with the patient's cells. The donor immune cells may recognize the patient's CML cells as foreign and kill them. This is called **graft versus leukemia**.

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Allogeneic stem cell transplantation can be a high-risk treatment. It is the only treatment that can cure CML. Gleevec® or other drugs can control CML in many patients for a long time. The decision to do a transplant depends on:

- Patient age
- Overall health
- How well the donor cells and patient cells “match”
- The patient’s response to drug therapy (the degree of cytogenetic and molecular response).

The decision also depends on the patient’s understanding of the benefits and risks of the transplant. If the doctor thinks a patient might benefit from a transplant, he or she will talk about these factors with the patient.

Allogeneic stem cell transplant is most successful in younger patients. Patients up to about 60 years of age who have a matched donor may be considered.

Doctors are studying a type of stem cell transplant called a **nonmyeloablative stem cell transplant** or **mini transplant**. It may be helpful for older patients. See page 24 for more information.

Donor Lymphocyte Infusion

CML patients whose disease returns after an allogeneic stem cell transplant (called a relapse) may be treated with Gleevec®, Spycel® or another CML drug. Another treatment choice is a second transplant. Or patients may be treated with a **donor lymphocyte infusion** (an infusion of white cells called lymphocytes from the original stem cell donor).

Doctors are studying a type of stem cell transplant called a nonmyeloablative stem cell transplant or **mini transplant**. It may be helpful for older patients. See page 24 for more information.

Autologous Stem Cell Infusion

Many CML patients cannot have an allogeneic stem cell transplant. Doctors are studying the use of a patient's own stem cells in these cases. This is called an **autologous stem cell infusion**.

Autologous means the patient's own cells are used. During the chronic phase of CML, stem cells are taken from the patient's blood or marrow and frozen. These stem cells may help the body make healthy blood cells after treatment. The stored stem cells are infused back into the patient's blood after treatment with chemotherapy ends.

Leukapheresis

Some patients have very high white cell counts at the time the doctor discovers their CML. This can reduce blood flow to the brain, lungs, eyes and other places in the body. Patients can have white cells removed by a machine. The process is called **leukapheresis**. A drug called hydroxyurea (Hydrea®) may also be used to decrease the white cell count. After the white cell count drops, Gleevec® can be started.

Leukapheresis can be used for patients diagnosed with CML in the first months of pregnancy, when drug therapy may be harmful to the unborn baby.

Related Disorders

There are other types of CML that do not involve the BCR-ABL gene. These other, less common types of CML are called **chronic myelomonocytic leukemia, juvenile myelomonocytic leukemia** and **chronic neutrophilic leukemia**.



For more information on these types of CML, see the Society's free fact sheet, *The Chronic Myelomonocytic Leukemias (CMML)*.

Clinical Trials

Clinical trials are used to study new drugs, new treatments or new uses for approved drugs or treatments.

Doctors are studying **other drugs** for CML.

- They are looking at whether nilotinib (Tasigna®) is useful in patients who cannot take Gleevec® because of severe side effects or poor response.
- They are studying whether Sprycel® would work as well or better than Gleevec® as a first treatment of chronic phase CML.

Check **Medical Terms** for words that are new to you.
Or call **The Leukemia & Lymphoma Society** at **(800) 955-4572**.

- They are also studying whether using more than one drug at the same time is more helpful than using a single drug.
- Doctors are studying other drugs that may help CML patients who do not respond to current treatment. One drug is VX-680. One of the purposes of this trial is to see if it can help patients in the blast crisis phase of CML.



The Society's free booklet, *Understanding Clinical Trials for Blood Cancers*, has more information about clinical trials.

Another goal of research for CML is to make a **vaccine**. This type of vaccine would not prevent the disease. Instead, the vaccine would increase the immune system's attack against remaining CML cells. The goal is to keep the disease in remission for a longer time.

Doctors are studying a type of stem cell transplant, called a **nonmyeloablative stem cell transplant** (or “mini transplant”). A **mini transplant** does not begin with high-dose chemotherapy. The patient takes special drugs so that his or her immune system does not reject the transplanted immune cells. Over a long time, the donated cells replace the patient’s blood and immune system cells. The donated cells also attack the CML cells.

Other drugs to help the transplanted stem cells fight the CML without attacking healthy cells are being tested in clinical trials.



Three CML vaccines under study, AG-858, CMLVAX and PR1 are described in the Society’s free publication, *Vaccine Therapy Facts*.

To order free booklets, contact **The Leukemia & Lymphoma Society** at www.LLS.org or **(800) 955-4572**.

Scientists are studying using **umbilical cord blood** as a source of stem cells for transplants in children and adults. This provides another possible source of matched, unrelated stem cells for patients without a matched, related stem cell donor. Results from cord blood stem cell transplants are promising.

Call The Leukemia & Lymphoma Society's Information Resource Center at 800-955-4572 to learn how you and your doctor can find out if participating in a clinical trial is right for you.

Talking to the Doctor

It may be helpful to write down questions to ask your doctor. Then you can write down your doctor's answers and review them later.

You may want to bring a family member or friend with you to the doctor. This person can listen, take notes and offer support. Some patients record information and listen to it at home.

Questions to Ask the Doctor

Talk with the doctor about CML. Ask how he or she plans to treat the disease. This will help you to be involved and make decisions.

Some questions to ask your doctor are:

- What do the blood and marrow tests show?
How do these results compare to “normal?”
- What kind of treatment do you think is needed?
- How much experience do you have treating CML patients?
- Will the treatment be paid for by my health plan?
- How often and how long will I (or my child) need treatment/follow-up visits? What type of follow-up tests will be needed?
- Should I (or my child) be treated in a cancer clinical trial?
- How will my treatment affect fertility, pregnancy or breastfeeding?
- What side effects should be expected from treatment?
- What can be done to help deal with side effects?
- What can I do to reduce the risk of infection?
- Will I (or my child) need to change our daily routine?
- How do I contact you after normal business hours?

To order free booklets, contact **The Leukemia & Lymphoma Society** at www.LLS.org or **(800) 955-4572**.

Coping with CML

Patients with CML should talk with their family, friends and caregivers about how they feel. They can share what they know about the disease. When family, friends and caregivers know about CML it helps them to cope.

It is important for patients with CML to:

- Keep all appointments with the doctor
- Take all medicines as instructed
- Follow the doctor's advice for preventing infection, such as avoiding crowds and washing hands
- Eat healthy foods each day; it is okay to eat 4 or 5 smaller meals instead of 3 larger meals
- Ask your treatment team for helpful tips if you don't feel like eating
- Get a balance of rest and exercise; speak to your doctor if you are not getting enough sleep
- Don't smoke – if you do, get help to quit
- Keep a health care file with copies of lab reports and treatment records
- See the family doctor to keep up with other health care needs.

The news that you or a loved one has CML brings up many feelings. People living with CML face many unknowns. You can talk about your concerns with the health care team. First you may want to focus on learning about CML and its treatment. You can then look ahead to taking care of yourself, remission and recovery.

Making treatment choices can cause a lot of stress. The time and money spent for medical care may be a burden. Ask your health care team for help. The team can give emotional support. They can refer you to other sources of help.

It is important to seek medical advice if a patient's mood does not improve over time – for example, if a person is feeling depressed every day for a two-week period.

Depression is an illness. It should be treated even when a person is being treated for CML. Treatment for depression has benefits for people living with cancer.

Children with a family member who has CML may need special attention. They may feel bad that their family member is sick. They may be sad or angry that their parents are not around as much.

Family, friends and caregivers can often help you cope with what lies ahead. Also, patients with CML may get to know one another. These friendships help too.

Today the outlook for a patient with CML is good. Most patients are able to keep their disease under control with medical treatment. They can live good quality lives. Some patients are cured with stem cell transplants (see page 19). New treatments and potential cures are on the horizon.



The Society's free booklets, *Each New Day* and *Coping: Support for People Living with Leukemia, Lymphoma or Myeloma*, and *Financial Health Matters*, have more on this topic.

Call Our Information Resource Center

The Society's Information Resource Center (IRC) provides patients, families and healthcare professionals with the latest information on leukemia, lymphoma and myeloma. Our information specialists – master's level oncology professionals – are available by phone (800.955.4572) Monday through Friday, 9 am to 6 pm (ET); via email (infocenter@LLS.org); or chat online at www.LLS.org (click on "Live Help").

Call 800.955.4572 for a complete directory of our patient services programs.



**The Leukemia &
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Fighting Blood Cancers

To order free booklets, contact **The Leukemia & Lymphoma Society** at www.LLS.org or (800) 955-4572.

30

The Leukemia & Lymphoma Society has free booklets.

Chronic Myelogenous Leukemia gives more detailed information about CML for patients and their families.

Blood and Marrow Stem Cell Transplantation is about stem cell transplantation.

Blood Transfusion provides information about blood transfusion for patients with leukemia, lymphoma or myeloma (blood cancers) and their families.

Coping and Each New Day: Ideas for People with Leukemia, Lymphoma or Myeloma are 2 booklets for patients and families living with blood cancers.

Financial Health Matters is about financial aid, insurance and ways to manage money.

Immunotherapy Fact Sheet provides information about the different types of immunotherapies and their roles in the treatment of blood cancers.

Long-Term and Late Effects of Treatment for Blood Cancers Fact Sheet describes some of the long-term and late risks associated with chemotherapy and radiation therapy.

Understanding Blood Counts, Choosing and Communicating with a Cancer Specialist and Choosing a Treatment Facility are fact sheets that may help you to know more about your health care.

Understanding Clinical Trials for Blood Cancers may help you understand and decide about clinical trials.

Understanding Drug Therapy and Managing Side Effects is about many cancer drugs and common side effects.

About or for Children

Emotional Aspects of Childhood Blood Cancers is written for parents of young children and adolescents with leukemia or lymphoma who seek support in facing and dealing with a difficult illness.

Learning & Living With Cancer: Advocating for Your Child's Educational Needs is about helping a child with cancer deal with school during and after treatment.

The Stem Cell Transplant Coloring Book supports children and helps them to express themselves throughout their treatment.

To order free booklets, contact **The Leukemia & Lymphoma Society** at www.LLS.org or **(800) 955-4572**.

Medical Terms

Anemia

Decrease in levels of hemoglobin in the blood.

Blast cells

Early bone marrow cells.

Chemotherapy

Treatment with drugs or medicines to kill leukemia cells.

Clinical trials

Studies that use volunteers to test new drugs, treatments or new uses for approved drugs or treatments.

FDA

Short name for the US Food and Drug Administration. The FDA looks at the results of drug studies and determines if a drug is safe and effective.

Hemoglobin

A substance in red blood cells that carries oxygen.

Immune system

Cells and proteins that defend the body against infection.

Leukapheresis

A process in which extra white cells are removed by a machine.

Medical Terms

Leukemia

A cancer of the marrow and blood.

Marrow

The spongy material in the center of bones where blood cells are made.

Relapse or recurrence

When disease comes back after it has been successfully treated.

Remission

No sign of the disease and/or a long time span when the disease is not causing any health problems for the patient.

Resistance

When a drug does not work or stops working.

Stem cell

A type of cell found in marrow that makes red cells, white cells and platelets.

Notes

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Notes

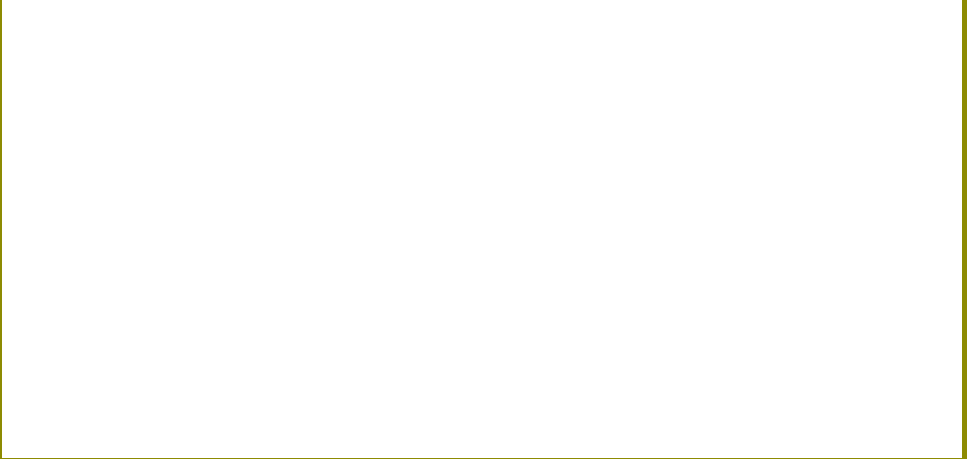
We're Here to Help

The Leukemia & Lymphoma Society has chapters around the nation. The Society's chapters offer support groups and also can arrange for a **CML** patient to talk with another person who has **CML**. **To find the Society's chapter in your area, call (800) 955-4572. Or go to www.LLS.org, the Society's Web site.**



To order free booklets, contact **The Leukemia & Lymphoma Society** at www.LLS.org or **(800) 955-4572**.

For more information, please contact:



or:

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White Plains, NY 10605

Information Resource Center (IRC) 800.955.4572

www.LLS.org

*Our Mission: Cure leukemia, lymphoma,
Hodgkin's disease and myeloma, and improve the
quality of life of patients and their families.*

The Society is a nonprofit organization that relies on the generosity of corporate and individual contributions to advance its mission.



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