

# PATIENT RESOURCE

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*5th Edition*

# CHRONIC LYMPHOCYTIC LEUKEMIA

A TREATMENT GUIDE FOR PATIENTS AND THEIR FAMILIES

→ *Living life  
with  
purpose*



*For guide to  
LEUKEMIA, LYMPHOMA & MULTIPLE MYELOMA*

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**AstraZeneca** 

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# CHRONIC LYMPHOCYTIC LEUKEMIA

5th Edition

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## Download your medication tracking worksheet

Use this worksheet to keep track of your CLL medications. See page 6 or download and print it at [PatientResource.com/CLLMedicalJournal.aspx](http://PatientResource.com/CLLMedicalJournal.aspx)

The form is titled "KEEPING TRACK MY CLL MEDICATION JOURNAL". It includes sections for "MY DIAGNOSIS" (Cancer Type/Subtype: Leukemia / chronic lymphocytic leukemia), "MY HEALTH CARE TEAM CONTACTS" (listing Oncologist/Specialist, Nurse Navigator, Primary Care Physician, Case Manager, and Pharmacy), and "MY MEDICATION TRACKER" (a table with columns for Date, Medication, Dosage/Frequency, Note the time you took your last dose, and Details of any side effect). A note at the top states: "Cancer-related therapies must be taken exactly as prescribed to be fully effective. Use this document to track each dose, including any missed doses. Make additional copies as needed. Share with your doctor during follow-up appointments."

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# YOU ARE NOT ALONE

with chronic lymphocytic leukemia (CLL)



CALQUENCE™ Connections is here for you—whether you are newly diagnosed, beginning a new treatment, or just seeking connections with other cancer patients.

Through the stories of patients on CALQUENCE and their caregivers, CALQUENCE Connections hopes to make you feel empowered while living with CLL.

## SIGN UP TO BECOME A PART OF THE CALQUENCE CONNECTIONS COMMUNITY

Or visit [CALQUENCEConnections.com](http://CALQUENCEConnections.com) for more information.

*If you cannot afford your medication, AstraZeneca may be able to help. Visit [AstraZeneca-us.com](http://AstraZeneca-us.com) to find out how.*

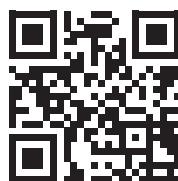
### Select Safety Information

CALQUENCE is a prescription oral treatment for adults with chronic lymphocytic leukemia or small lymphocytic lymphoma. May cause serious side effects including: serious infections, bleeding problems, decrease in blood cell count, new cancers, and heart rhythm problems. Some may lead to death. Tell your doctor if you experience infections such as flu-like symptoms; unexpected bleeding such as blood in your stool or urine; or heart rhythm problems such as fast or irregular heartbeat. Use sun protection when outside.

### Please read Brief Summary of Prescribing Information on adjacent page.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch) or call 1-800-FDA-1088.

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# PATIENT INFORMATION

## CALQUENCE® (KAL-kwens) (acalabrutinib) capsules



**CALQUENCE®**  
(acalabrutinib) 100 mg capsules

### What is CALQUENCE?

CALQUENCE is a prescription medicine used to treat adults with:

- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

It is not known if CALQUENCE is safe and effective in children.

### Before taking CALQUENCE, tell your healthcare provider about all of your medical conditions, including if you:

- have had recent surgery or plan to have surgery. Your healthcare provider may stop CALQUENCE for any planned medical, surgical, or dental procedure.
- have bleeding problems.
- have or had heart rhythm problems.
- have an infection.
- have or had liver problems, including hepatitis B virus (HBV) infection.
- are pregnant or plan to become pregnant. CALQUENCE may harm your unborn baby and problems during childbirth (dystocia).
  - If you are able to become pregnant, your healthcare provider may do a pregnancy test before you start treatment with CALQUENCE
  - Females who are able to become pregnant should use effective birth control (contraception) during treatment with CALQUENCE and for at least 1 week after the last dose of CALQUENCE.
- are breastfeeding or plan to breastfeed. It is not known if CALQUENCE passes into your breast milk. Do not breastfeed during treatment with CALQUENCE and for at least 2 weeks after your final dose of CALQUENCE.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking CALQUENCE with certain other medications may affect how CALQUENCE works and can cause side effects. Especially tell your healthcare provider if you take a blood thinner medicine.

### How should I take CALQUENCE?

- Take CALQUENCE exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking CALQUENCE unless your healthcare provider tells you to.
- Your healthcare provider may tell you to decrease your dose, temporarily stop, or completely stop taking CALQUENCE if you develop certain side effects.
- Take CALQUENCE 2 times a day (about 12 hours apart).

(continued)

- Take CALQUENCE with or without food.
- Swallow CALQUENCE capsules whole with a glass of water. Do not open, break, or chew capsules.
- If you need to take an antacid medicine, take it either 2 hours before or 2 hours after you take CALQUENCE.
- If you need to take certain other medicines called acid reducers (H-2 receptor blockers), take CALQUENCE 2 hours before the acid reducer medicine.
- If you miss a dose of CALQUENCE, take it as soon as you remember. If it is more than 3 hours past your usual dosing time, skip the missed dose and take your next dose of CALQUENCE at your regularly scheduled time. Do not take an extra dose to make up for a missed dose.

### What are the possible side effects of CALQUENCE?

#### CALQUENCE may cause serious side effects, including:

- **Serious infections** can happen during treatment with CALQUENCE and may lead to death. Your healthcare provider may prescribe certain medicines if you have an increased risk of getting infections. Tell your healthcare provider right away if you have any signs or symptoms of an infection, including fever, chills, or flu-like symptoms.
- **Bleeding problems (hemorrhage)** can happen during treatment with CALQUENCE and can be serious and may lead to death. Your risk of bleeding may increase if you are also taking a blood thinner medicine. Tell your healthcare provider if you have any signs or symptoms of bleeding, including:
  - blood in your stools or black stools (looks like tar)
  - pink or brown urine
  - unexpected bleeding, or bleeding that is severe or you cannot control
  - vomit blood or vomit that looks like coffee grounds
  - cough up blood or blood clots
  - dizziness
  - weakness
  - confusion
  - changes in your speech
  - headache that lasts a long time
  - bruising or red or purple skin marks

#### • Decrease in blood cell counts.

Decreased blood counts (white blood cells, platelets, and red blood cells) are common with CALQUENCE, but can also be severe. Your healthcare provider should do blood tests to check your blood counts regularly during treatment with CALQUENCE.

(continued)

- **Second primary cancers.** New cancers have happened in people during treatment with CALQUENCE, including cancers of the skin or other organs. Your healthcare provider will check you for skin cancers during treatment with CALQUENCE. Use sun protection when you are outside in sunlight.

- **Heart rhythm problems (atrial fibrillation and atrial flutter)** have happened in people treated with CALQUENCE. Tell your healthcare provider if you have any of the following signs or symptoms:
  - fast or irregular heartbeat
  - dizziness
  - feeling faint
  - chest discomfort
  - shortness of breath

### The most common side effects of CALQUENCE include:

- headache
- diarrhea
- muscle and joint pain
- upper respiratory tract infection
- bruising

These are not all of the possible side effects of CALQUENCE.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### How should I store CALQUENCE?

- Store CALQUENCE at room temperature between 68°F to 77°F (20°C to 25°C).

### Keep CALQUENCE and all medicines out of the reach of children.

### General information about the safe and effective use of CALQUENCE.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use CALQUENCE for a condition for which it was not prescribed. Do not give CALQUENCE to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for more information about CALQUENCE that is written for health professionals.

### What are the ingredients in CALQUENCE?

**Active ingredient:** acalabrutinib

**Inactive ingredients:** silicified microcrystalline cellulose, pre-gelatinized starch, magnesium stearate, and sodium starch glycolate.

Capsule shell contains: gelatin, titanium dioxide, yellow iron oxide, FD&C Blue 2, and black ink.

**AstraZeneca**

For more information,  
go to [www.CALQUENCE.com](http://www.CALQUENCE.com)  
or call 1-800-236-9933.

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# Planning provides a framework for managing a CLL diagnosis

**C**hronic lymphocytic leukemia (CLL) is a type of hematologic (blood) cancer. It is usually slow-growing and, at this time, is a condition that is managed, not cured. Though a CLL diagnosis is life-changing, the landscape of CLL research is very promising. More effective drugs and combination treatments are now available for this chronic blood cancer.

For many people, a CLL diagnosis is a complete surprise because symptoms usually are not present in the beginning. It is often discovered by accident through routine blood-work or another issue. As a result, you may think you feel too good to have cancer, so it may be difficult to decide what to do first.

Give yourself time to digest the news, then begin to research. You will find that the timing of treating CLL may be unlike that of other types of cancer you are familiar with, so it will help to learn about CLL. This guide is a great place to start.

## GETTING STARTED

Moving forward with confidence is easier with a plan. You may consider choosing a hematologist with expertise in treating CLL. Specialists better understand CLL and how it responds to treatment. They can offer treatment plans that help many people live longer and with a better quality of life.

Your diagnosing physician should be able to give you a referral. If you are not located near a CLL specialist and traveling for treatment is not an option, look for a CLL specialist who will consult with your doctor and offer a second opinion. This can confirm the suggested treatment plan or add other options to consider.

Commit to taking an active role in your care. While your doctor monitors your test results,

you will need to communicate honestly about symptoms and treatment-related side effects. It will also be up to you to keep in-person and telehealth appointments and make wise nutrition and lifestyle choices.

## EXPLAINING CLL

Leukemia begins in the blood and bone marrow (the soft, spongy center of some bones). It occurs when the bone marrow makes too many white blood cells. These white blood cells don't fight infection like healthy white blood cells do, which makes an individual susceptible to repeated infections.

CLL develops from a type of white blood cell known as a lymphocyte. Lymphocytes make up lymphoid tissue, which is found in the lymph nodes, thymus, spleen, tonsils and other parts of the body. They are a part of the immune system.

CLL begins when mature lymphocytes change and multiply uncontrollably. They grow at a faster rate than usual, and they do not die when they should, causing them to build up in the blood or bone marrow. This leads to an accumulation of them in the blood, bone marrow, lymph nodes and spleen that interferes with the normal production of healthy cells, including red blood cells that carry oxygen; white blood cells that fight infection; and platelets that help blood to clot.

Except for lymphomas, blood cancers typically do not grow into tumors. Instead, abnormal lymphocytes build up to become CLL cancer cells that circulate in the bloodstream and can spread through the lymphatic system to other parts of the body. However, patients with CLL often have larger than normal lymph nodes that can appear as lumps in the neck, armpits or groin regions.

## DIAGNOSING & PLANNING

Your doctor will perform a physical examination to check for pain, enlarged lymph nodes and size irregularity in your spleen and other organs. Blood test results help determine your prognosis (outlook).

To identify your CLL subtype, your doctor will order genetic testing, also called molecular profiling, on a small sample of fluid or tissue. The results of these tests, including a fluorescence in situ hybridization (FISH) test, your TP53 gene mutation status, immunoglobulin heavy chain variable (IGHV) status, and serum B2-microglobulin concentration, help identify specific gene abnormalities or mutations, proteins and changes in chromosomes.

The Modified Rai Staging System and the Chronic Lymphocytic Leukemia International Prognostic Index (CLL-IPI) further assist your doctor (see Tables 1 and 2). Modified Rai divides CLL into five stages according to the number of lymphocytes and other cells in the blood and the presence of certain abnormalities noticed on the physical examination. The "risk" characteristic assigned in staging is associated with the predicted rate of growth for the disease. This offers information about how CLL may progress. CLL-IPI is used to predict the risk of disease recurrence and overall survival and incorporates the Rai stage.

Your doctor will also consider the clinical stage, your age and other criteria.

This information will help determine the treatment that will be most effective. ■

**TABLE 1  
MODIFIED RAI STAGING SYSTEM**

| Stage            | Risk         | Description   |
|------------------|--------------|---|
| <b>Stage 0</b>   | Low          | Lymphocytosis only (the blood contains a significant number of lymphocytes).  |
| <b>Stage I</b>   | Intermediate | + Adenopathy (the blood contains a significant number of lymphocytes, and lymph nodes are enlarged).  |
| <b>Stage II</b>  | Intermediate | + Enlarged spleen and/or liver (the blood contains a significant number of lymphocytes, the spleen and/or liver is enlarged, and the lymph nodes may or may not be enlarged). |
| <b>Stage III</b> | High         | Lymphocytosis + Hgb < 11g/dL (the blood contains a significant number of lymphocytes, and the hemoglobin is less than 11 grams per deciliter).                                |
| <b>Stage IV</b>  | High         | Lymphocytosis + Plt < 100,000/ $\mu$ L (the blood contains a significant number of lymphocytes, and the platelet count is less than 100,000 microliters).                     |

In addition to this staging system, some oncologists may also use the Chronic Lymphocytic Leukemia International Prognostic Index (CLL-IPI) to predict the risk of disease recurrence and overall survival. Your doctor, after evaluating your physical examination and diagnostic test results, takes into account your TP53 status, IGHV mutation status, serum B2-microglobulin concentration, clinical stage and age.

The CLL-IPI assigns weighted values for each of the following risk factors:

- TP53 mutation = 4 points
- IGHV unmutated = 2 points
- Serum B2-microglobulin more than 3.5mg/L = 2 points
- Rai Stages I-IV
- Age older than 65 years = 1 point

Used with permission of the American Joint Committee on Cancer (AJCC), Chicago, Illinois. The original and primary source for this information is the AJCC Cancer Staging Manual, Eighth Edition (2017) published by Springer Science+Business Media.

**TABLE 2  
CHRONIC LYMPHOCYTIC LEUKEMIA  
INTERNATIONAL PROGNOSTIC INDEX (CLL-IPI)**

| The CLL-IPI assigns weighted values for each of the following risk factors. |        |
|---|--------|
| Risk factors  | Points |
| <b>TP53 mutation</b>  | 4      |
| <b>IGHV unmutated</b>   | 2      |
| <b>Serum B2-microglobulin more than 3.5 mg/L</b>                            | 2      |
| <b>Rai Stages I-IV</b>  | --     |
| <b>Age older than 65 years</b>  | 1      |

# Partner with your medical team to chart your course

**T**he goal of treatment for chronic lymphocytic leukemia (CLL) is to reach remission — no signs or symptoms of cancer. Currently, CLL is managed like a chronic disease. Although there is no cure for CLL at this time, research continues to uncover new and better ways of treating it, and more treatment options are available today with more expected in the coming years. Keep in mind that your treatment plan will likely change as the disease changes to ensure it continues to be managed most effectively.

When you are first diagnosed with CLL, your immediate reaction may be to start treatment right away while you feel healthy enough to do so. But unless you are experiencing certain symptoms or your blood test results deem it necessary, your doctor may recommend waiting to begin treatment to spare you from side effects that could disrupt your quality of life. Unlike other cancers that are aggressive and may need immediate treatment, research shows that treating CLL early does not improve the outcome.

Instead of beginning treatment with medication, you and your medical team will monitor your condition together during what's called active surveillance, sometimes referred to as watchful waiting. It is often recommended for low-stage or low-risk CLL.

You may find this treatment approach unsettling because it feels as if you are not taking action. However, being a responsible patient and doing your part is taking action.

As your medical team monitors you through tests and physical exams, you will be responsible for keeping follow-up appointments and alerting your medical team immediately if you experience any symptoms that indicate the disease is progressing. Some symptoms and reasons to start treatment include the following:

- Unexplained weight loss
- Severe fatigue
- Fevers above 100.4° F without evidence of infection
- Drenching night sweats
- Spleen or lymph node enlargement
- A decreasing number of red blood cells or platelets
- Treatment with steroids is no longer working and your body is killing your blood cells (autoimmune cytopenia)
- Even if symptoms don't yet indicate you need treatment, you may choose to enroll in a clinical trial.

## TREATMENT OPTIONS

Clinical trials may offer access to leading-edge therapies not yet approved by the U.S. Food and Drug Administration. They may also be the best first treatment option for your specific diagnosis. Clinical trials are studies that evaluate whether a new treatment, such as a drug or vaccine, drug combination, surgical procedure, type of radiation therapy or a combination of therapies is more effective or better in some way than the current standard of care. A great deal of progress continues to be made in the ways doctors treat CLL, including trials using

chimeric antigen receptor (CAR) T-cell therapy (see *Fictional Case Study*, page 8).

**Targeted therapy** is a personalized strategy that enables your doctor to use the results from your genetic (molecular) testing to target specific genes and proteins that are causing cancer cells to grow and multiply.

It is commonly the first treatment given for CLL. Types of targeted therapies used for CLL include the following:

- Tyrosine kinase inhibitors (TKIs) block certain substances that control how cells grow and divide. One type called a Bruton's tyrosine kinase (BTK) inhibitor blocks the BTK protein, which may promote the growth of abnormal B-cells.
- BCL2 inhibitors block the BCL2 protein, which is found on some leukemia cells.
- Monoclonal antibodies are laboratory-made immune system proteins that attach to a specific target on cancer cells or other cells that may help cancer grow. The antibodies are then able to kill the cancer cells, block their growth or keep them from spreading.

Using targeted therapy allows your medical team to control the disease while limiting damage to healthy cells, which may result in fewer side effects. Some targeted therapy drugs are oral medications given in pill form, and others are given intravenously (IV). Some may be used alone or in combination with other therapies.

**Corticosteroids**, anti-inflammatory drugs that appear to help cause the death of cancerous

## MANAGING YOUR CLL

*Living with a chronic disease means taking actions to keep yourself as healthy as possible. To do that, learn everything you can about potential side effects from the disease and/or treatment as well as how to manage appointments required.*

**Make healthy lifestyle choices.** Focus on making positive choices in many areas of your life, such as staying active, following a healthy diet, reducing your risk for infection, caring for your emotional well-being and surrounding yourself with support. Research shows exercising and following a nutritious diet offers many health benefits, including helping you be better prepared for future health issues.

**Learn about potential side effects.** Most cancer treatments have side effects, but you likely won't experience all of them. People respond differently, even to the same diagnosis and type of treatment. Learn about the possible treatment-related side effects you need to be aware of before starting treatment. Your health care team may provide you with a list of symptoms to watch for. Some may indicate the cancer is progressing, and your treatment plan may need to be re-evaluated.

Keep in mind that side effects may be more intense when treatments are given in combination.

Severe side effects aren't common but can occur with certain types of treatment. Ask if you are at risk, how you can identify the signs and what to do if they occur. Prompt treatment may help prevent more serious complications.

Late effects are side effects that do not begin immediately during treatment. They may appear weeks, months or even years after treatment begins. Just as with other side effects, every person reacts differently and some people may not have them at all. They may go away over time; others may be permanent. They often depend on the type of treatment and the length of time it was given, as well as your age, gender and overall health.

## PATIENT ASSISTANCE RESOURCES

*For more resources, flip over this guide and see page 35.*

- **myAbbVie Assist:** [www.abbvie.com/patients/patient-assistance](http://www.abbvie.com/patients/patient-assistance)
- **Arzerra Oncology Access Program:** [us.arzerra.com](http://us.arzerra.com)
- **AstraZeneca Access 360:** [www.myaccess360.com/patient](http://www.myaccess360.com/patient)
- **Bendeka CORE:** [bendeka.com/support/assistance](http://bendeka.com/support/assistance)
- **Calquence Cares:** [www.calquence.com/cll/support-for-patients](http://www.calquence.com/cll/support-for-patients)
- **Gazyva Financial Assistance:** [www.gazyva.com/first-line-cll/financial-support/ways-to-save.html](http://www.gazyva.com/first-line-cll/financial-support/ways-to-save.html)
- **Genentech Access Solutions:** [www.genentech-access.com/patient.html](http://www.genentech-access.com/patient.html)
- **Gilead's Advancing Access:** [www.gileadadvancingaccess.com](http://www.gileadadvancingaccess.com)
- **GSK For You:** [www.gskforyou.com](http://www.gskforyou.com)

white blood cells, are sometimes given along with other drug therapies.

**Chemoimmunotherapy** combines chemotherapy with immunotherapy. It may be used for CLL that does not have the *TP53* mutation.

**Radiation therapy** may be used to shrink an enlarged spleen or swollen lymph nodes, relieve certain symptoms or assist in the conditioning phase of a stem cell transplant.

#### OTHER TREATMENTS

An **allogeneic stem cell transplant**, which uses stem cells from a volunteer donor, may be used to treat CLL. The goal of transplantation is for your blood counts to return to safe levels and/or remission, which is having no signs or symptoms of cancer. (Flip over this guide to see *Stem Cell Transplantation*, page 8.)

**Chemotherapy** may be used in some instances and combined with other therapies. It may be given in high doses before stem cell transplantation in a process known as conditioning.

**Surgery** may be recommended in cases where the spleen is enlarged and needs to be removed (splenectomy).

#### RELAPSED AND REFRACTORY CLL

Because CLL is a chronic condition, it may return in different ways. Following are descriptions of various states of CLL.

**Complete remission:** All signs and symptoms of cancer have disappeared but cancer may still be in the body.

**Lower your risk of infection.** People with CLL often have a weaker immune system, which may make them more susceptible to developing infections. Infections while you are already managing CLL can become serious, making it important to detect and treat infections as soon as they start. Your doctor will talk with you about the signs to watch for and what to do if they occur.

Another way to reduce your risk of infections is to stay up to date with your vaccinations and health screenings for other cancers. Vaccinations may include shots for the flu, pneumonia, shingles, COVID-19 and others. Remember to continue to get regular screenings, such as mammograms, colonoscopies, skin exams, Pap smears, HPV testing, prostate specific antigen (PSA) blood tests and any additional testing your doctor recommends.

**Consider telehealth options.** Telehealth is accessing medical care from a distance through technology. It may be a way to report symptoms and stay in touch with your doctor between in-person follow-up

#### DRUG THERAPIES FOR CLL

*These therapies may be used alone or in combination. Some possible combination therapies are listed below.*

- acalabrutinib (Calquence)
- bendamustine (Bendeka)
- chlorambucil (Leukeran)
- cyclophosphamide
- dexamethasone
- doxorubicin hydrochloride (Adriamycin)
- duvelisib (Copiktra)
- fludarabine phosphate (Fludara)
- ibrutinib (Imbruvica)
- idelalisib (Zydelig)
- methylprednisolone
- obinutuzumab (Gazyva)
- ofatumumab (Arzerra)
- prednisone
- rituximab (Rituxan)
- venetoclax (Venclexta)
  
- FC: fludarabine phosphate and cyclophosphamide
- FCR: fludarabine phosphate, cyclophosphamide and rituximab (Rituxan) or rituximab and hyaluronidase human (Rituxan Hycela)
- FR: fludarabine phosphate and rituximab (Rituxan)
- ibrutinib (Imbruvica) with bendamustine (Bendeka) and rituximab (Rituxan)
- ibrutinib (Imbruvica) with rituximab (Rituxan)
- idelalisib (Zydelig) and rituximab (Rituxan) for patients with recurrent CLL
- obinutuzumab (Gazyva) and chlorambucil (Leukeran) for older patients
- ofatumumab (Arzerra) with chlorambucil (Leukeran)
- ofatumumab (Arzerra) with fludarabine and cyclophosphamide
- rituximab and hyaluronidase human (Rituxan Hycela) with fludarabine and cyclophosphamide
- VEN+G: venetoclax (Venclexta) with obinutuzumab (Gazyva)
- VEN+R: venetoclax (Venclexta) with rituximab (Rituxan)

As of 10/13/21

#### SOME POSSIBLE COMBINATION THERAPIES

- acalabrutinib (Calquence) and obinutuzumab (Gazyva)
- BR: bendamustine (Bendeka) and rituximab (Rituxan)

**Minimal residual disease (MRD):** A term used to describe a very small number of cancer cells that remain in the body during or after treatment. Specialists use highly sensitive laboratory tests to find one cancer cell among one million normal cells. This information helps your doctor to plan further treatment and monitor to determine if the treatment is working or if cancer has returned.

**Partial remission:** Leukemia levels are significantly reduced but there is still evidence of some leukemia cells.

**Refractory CLL:** Cancer that does not respond or improve with treatment. Several options are available to treat refractory CLL. Your doctor

will take into account the options you have already tried and your overall health before recommending another plan. This may be a good time to consider getting a second opinion, especially if your doctor doesn't specialize in CLL. You may also consider clinical trials.

**Relapsed (or recurrent) CLL:** Cancer that has come back, usually after a period of time during which the cancer could not be detected. If this occurs, your doctor will begin a new cycle of diagnostic tests, which may include another biopsy and laboratory tests. Your doctor will confirm whether the cancer is recurrent and whether it has transformed into a more aggressive subtype, which will affect your new treatment plan. ■

appointments. Virtual appointments are not designed to replace in-person visits, but they do provide you with a convenient alternative. They may be a welcome option, especially if you are in remission, taking oral-based therapies or receiving maintenance therapy, or you have already had your initial consultation and may not need an in-person visit.

**Attend follow-up visits.** These appointments are important for catching a recurrence early, addressing any side effects or issues and monitoring you for second cancers. A second cancer is a completely different or new type of cancer diagnosis.

Your doctors will monitor you closely through regularly scheduled appointments. During these visits, you will have exams and lab tests to look for physical signs of CLL and to measure how well the CLL is responding to current treatment. When your treatment is no longer working or is not as effective as it once was, your doctor may try another therapy.

- **Imbruvica By Your Side Patient Support:** [www.imbruvica.com/imbruvica-by-your-side](http://www.imbruvica.com/imbruvica-by-your-side)
- **Rituxan Financial Assistance:** [www.rituxan.com/nhl-cll/financial-assistance](http://www.rituxan.com/nhl-cll/financial-assistance)
- **Teva CORE:** [www.tevacore.com](http://www.tevacore.com)
- **Verastem Cares:** [www.copiktra.com/patient-assistance](http://www.copiktra.com/patient-assistance)
- **Novartis Patient Assistance Foundation:** [patientassistance.now.com](http://patientassistance.now.com)
- **Secura Bio Patient Support Programs:** [securabio.com/](http://securabio.com/)
- **Venclexta Access Solutions:** [genentech-access.com/patient/brands/venclexta](http://genentech-access.com/patient/brands/venclexta)
- **Zydelig Patient & Caregiver Support:** [www.zydelig.com/resources/patient-caregiver-resources](http://www.zydelig.com/resources/patient-caregiver-resources)



**Diagnosed with chronic lymphocytic leukemia at 62, Tony Donk quickly discovered the power of a strong support system. He credits his family, medical team and friends with helping him continue to live a happy, active life.**

## Round up a terrific support system

### Massaging a knot on my neck didn't make

it go away. It only got bigger. And then another one appeared below it. After a round of antibiotics, a needle biopsy and surgery to remove one of the swollen lymph nodes, what I hoped might be just an infection was diagnosed as chronic lymphocytic leukemia (CLL).

My wife is a 10-year breast cancer survivor and was treated at a comprehensive cancer center not far from our home. Our experience there was excellent. They coordinated everything for us, from consultations and appointments to tests and procedures. It took the pressure off of us to know what to do, so we immediately went there for my care.

I expected to meet my oncologist, get treated and life would move on. That's not the way it happened. First, I was told CLL is not curable. It does, however, respond well to treatment, so that was a plus. Then I found out my CLL hadn't progressed enough to need treatment. That put me into a period of watchful waiting. Although it made sense not to treat until it was necessary, it was a little discombobulating.

My oncologist planned to monitor my lymph nodes and blood levels very carefully, and she made a deal with me. It was her job to let me know when she was concerned. It was my job to live as healthfully as I could.

I met with a nutritionist who helped me think through healthier options. For me, that meant minimizing sugar because I have a fatty liver. Too much sugar combined with CLL is not good.

Our deal also included me staying off the internet. There are a lot of worst-case cancer scenarios out there, and she reminded me that every person's diagnosis is unique and no one responds to treatments in the same way. That was very good advice because cancer is an anxiety-inducing diagnosis — and I had some anxiety, especially early on.

A year after my diagnosis, test results showed it was time to begin treatment. My oncologist gave me two options: a daily oral targeted therapy or chemotherapy combined with immunotherapy. I opted for the more convenient daily pill. She explained that targeted therapies eventually stop being effective, but when that happens, she will have another candidate. And, I would still have the combination therapy option.

### My advice to you...

Remember that treating CLL doesn't mean curing it. It means getting back to feeling better.

Explore a comprehensive cancer center, if possible.

Put seeing a social worker or therapist high on your list. Even though I'm managing my CLL, I still have cancer. Regularly checking in with a therapist who has experience working with people who have chronic illnesses helps.

Round up your own support system filled with people who aren't afraid to ask how you're doing.



Four months after starting the therapy, my white blood cell count looked good and my other numbers were headed in the right direction. I'm still on that same therapy, and I've had minimal side effects.

Part of my care included access to a therapist at the cancer center. I made an appointment, then cancelled it.

After all, between my wife, kids, friends and oncologist, I already had a terrific support system. At my wife's urging, I finally rescheduled, thinking that I'd meet the person and develop a relationship just in case. But, I felt like I'd struck gold. I left that first meeting with a long list of future appointments! Even the therapist suggested we might not need so many. It was just incredibly helpful to talk with a professional. And, I realized that it was unfair to expect my wife to be my therapist. Sometimes I have very serious worries that I don't want to burden her with; other times, I just need someone else to listen.

As a literacy professor at a small liberal arts college, I'm a writer but had never written a blog. My wife encouraged me to start one. Along with being an outlet for expressing my feelings, it's helped educate my friends. Cancer is an uncomfortable topic, and often people don't know how to talk about it. Or, they are so afraid to say the wrong thing that they don't say anything at all. I used my blog to talk about my diagnosis, and that has helped my friends feel more comfortable with my condition. Now, when someone asks how I feel or what my latest test results show, I know they care, and I appreciate it.

Having an incurable condition changes your outlook on a lot of things. It's not all bad, just different. Our family has always done what we wanted when we wanted to, but CLL is limiting. I was diagnosed in 2016 at 62 years old, and retirement is fast approaching, but now we can't just take off for three months because I have to be back for monthly follow-up tests. I'm hopeful my oncologist and I can figure out something in the future. ■



# The path to a clinical trial

**Dave, age 54** (*Dave is not a real patient.*)

**Diagnosis:** Chronic Lymphocytic Leukemia

→ Bloodwork from Dave's annual physical came back suspect, so his primary care physician referred him to a hematologist who specializes in blood disorders.

After performing more diagnostic tests, the doctor confirmed a diagnosis of chronic lymphocytic leukemia (CLL). Because the disease was in the early stage and Dave wasn't experiencing any symptoms, his doctor recommended active surveillance — watching for signs that treatment should begin.

Aside from just learning he had cancer, Dave felt strong and told the doctor he wanted to be proactive with treatment. His doctor explained that treating before it is necessary is not helpful, and it may even introduce side effects and other complications, especially if he has any other health issues. He also told Dave that early treatment wouldn't make a difference long term, and it would not cure the CLL.

He went on to describe how both he and Dave would have important roles in monitoring the CLL. Follow-up appointments would happen every six months. While he would watch for trends in Dave's blood test results that could signal a need to begin treatment, Dave would let him know as soon as he felt any physical symptoms, such as fatigue, swollen lymph nodes and drenching night sweats.

Once Dave understood that he would have an active role in his treatment, he felt more confident. He continued working, exercising and enjoying life.

During active surveillance, Dave had researched reputable sources to learn more about CLL. He also joined a CLL support group. Both helped him better understand how the disease is treated. For example, he discovered that one treatment may not be enough. Sometimes CLL treatments stop working or become less effective. And, CLL tends to come back.

A few years later, Dave's blood tests showed a trend of decreasing platelet and red blood cell counts, and he had night sweats, felt fatigued and was losing weight. His doctor said it was time to begin treatment.

The doctor ordered tests to determine the presence of any biomarkers, as those would help him determine the most effective therapy.

Dave also sought an opinion from a CLL expert physician and found out that he had an unmutated *IGHV* and *deletion 17p* with a *TP53* mutation. All of these factors predicted that the disease would be more aggressive. Given his worsening symptoms and blood counts and enlarging lymph nodes, he took his doctor's recommendation and pursued treatment with a targeted therapy designed to treat *deletion 17p*.

The targeted therapy worked really well. Dave had minimal side effects, felt better and his symptoms and blood counts improved.

After three years, his doctor began to notice a slow increase in the number of CLL cells in the blood. Additional testing demonstrated the presence of resistance to that targeted therapy. He also started having some of the same symptoms he had experienced previously.

Based on all of these factors, Dave's doctor gave him two options that were specifically designed for patients for whom the targeted therapy Dave took first was no longer effective. One was a different targeted therapy. The other was a clinical trial involving chimeric antigen receptor (CAR) T-cell therapy (see below). The potential result of this option could be that the CAR T-cells would eradicate all the cancer cells in Dave's body. And, because they are a form of immunotherapy, the CAR T-cells would remain in his body, working to guard against recurrence for some time.

To help him make a confident decision, Dave's doctor explained the clinical trials process in general. Although both options appealed to Dave, he liked the idea of contributing to the future of cancer care by participating in a clinical trial, and the potential long-term effectiveness of CAR T-cell therapy appealed to him.

He chose a CAR T-cell clinical trial as his next line of treatment. ■

Dave, age 54  
Diagnosis: Chronic Lymphocytic Leukemia

## CAR T-CELL THERAPY

### STEP 1: OUTPATIENT

Your blood is taken so your T-cells can be removed.



Your T-cells are sent to a lab, where chimeric antigen receptors (CARs) are added to help them attack cancer cells.



These modified cells, now called CAR T-cells, are multiplied into the millions.

While your T-cells are being modified, you are given chemotherapy to deplete your immune system to give your new CAR T-cells a fresh environment in which to grow. This is called conditioning.

### STEP 2: INPATIENT

Your CAR T-cells are infused back into your body during an approximate two-week hospital stay.



The CAR T-cells will continue to multiply and attack cancer cells for a long time. After being discharged, you will have frequent follow-up appointments for months to check the treatment's effectiveness.

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