GAZYVA for Chronic Lymphocytic Leukemia (CLL)

GAZYVA is a prescription medicine used with the chemotherapy drug, chlorambucil, to treat chronic lymphocytic leukemia (CLL) in adults who have not had previous CLL treatment.

WHAT IS THE MOST IMPORTANT SAFETY INFORMATION I SHOULD KNOW ABOUT GAZYVA?

Tell your doctor right away about any side effect you experience. GAZYVA can cause side effects that can become serious or life threatening, including:

• Hepatitis B Virus (HBV): Hepatitis B can cause liver failure and death. If you have a history of hepatitis B infection, GAZYVA could cause it to return. You should not receive GAZYVA if you have active hepatitis B liver disease. Your doctor or healthcare team will need to screen you for hepatitis B before, and monitor you during and after, your treatment with GAZYVA. Sometimes this will require treatment for hepatitis B. Symptoms of hepatitis include: worsening of fatigue and yellow discoloration of skin or eyes

• Progressive Multifocal Leukoencephalopathy (PML): PML is a rare and serious brain infection caused by a virus. PML can be fatal. Your weakened immune system could put you at risk. Your doctor will watch for symptoms. Symptoms of PML include: confusion, difficulty talking or walking, dizziness or loss of balance, and vision problems

Please see pages 18-23 and accompanying full Prescribing Information for additional Important Safety Information, including BOXED WARNINGS.
Your doctor says it is time to treat your chronic lymphocytic leukemia (CLL) with GAZYVA® (obinutuzumab).

You may have a few questions. This guide will help explain CLL and your course of treatment with GAZYVA.

Please contact your healthcare treatment team with any questions that you may have.

Who should not receive GAZYVA?
- Do NOT receive GAZYVA if you have had an allergic reaction (eg, anaphylaxis or serum sickness) to GAZYVA. Tell your healthcare provider if you have had an allergic reaction to obinutuzumab or any other ingredients in GAZYVA in the past.

The information provided in this brochure is meant for informational purposes only. It is not meant to replace your physician’s medical advice.
In this guide:

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Certain medical terms used in this guide in **bold** and *underlined* will be defined in the Glossary.
What is CLL?

CLL stands for **chronic lymphocytic leukemia**. It is a type of blood cancer that involves **lymphocytes**—white blood cells that help fight infections. When you have CLL, abnormal lymphocytes build up in the blood and **bone marrow**. Over time, these abnormal cells crowd the healthy cells. The result is fewer healthy white blood cells, red blood cells, and **platelets**. This leads to problems such as infection, **anemia**, and excess bruising and bleeding. Abnormal lymphocytes may also build up in **lymph nodes**, the liver, or the **spleen** (an organ in your abdomen). This can lead to swelling of these organs.
What are the symptoms of CLL?

Everyone experiences CLL differently. CLL does not always cause symptoms. In early stages of CLL, you are less likely to be bothered by symptoms. Still, it is important to pay attention to how your CLL may be affecting you. Tell your doctor if you notice any symptoms or changes in your health.

The symptoms you should watch for include:

- Weakness
- Feeling tired
- Feeling short of breath
- Weight loss
- Fever
- Night sweats

- Enlarged lymph nodes (felt as lumps under the skin)
- Pain or a sense of “fullness” in the belly (especially after eating a small meal)
- Infections
- Excess bruising and bleeding

Symptoms of CLL may be seen in other conditions as well. Only your doctor will be able to tell if your symptoms are related to CLL.

Your doctor will be looking for:

- An increase in the number of abnormal white blood cells
- A decrease in the number of normal blood cells
- Swelling in your lymph nodes, liver, or spleen

Worsening of symptoms is reason to start treatment for CLL. Remember to talk with your healthcare team.
Understanding medical tests for CLL

CLL cannot be diagnosed by symptoms alone. In fact, you are often not the first to notice your CLL. CLL is usually detected by routine checkups, or blood work for other health issues. Your doctor will need to use medical tests to diagnose your CLL. Medical tests will also tell where CLL is in your body.

**Common tests for diagnosis or prior treatment:**

- **Physical exam**—your doctor checks for swollen lymph nodes, liver, or spleen and other signs of CLL
- **Blood cell counts**—your blood is taken through a vein and examined in a lab. Most people with CLL have a high white blood cell count
- **Biopsy**—a small sample of bone marrow or lymph node is removed and viewed under a microscope
- **Flow cytometry**—a sample of your cells is examined using a laser beam and a computer to find out the type of cancer and the number of cells involved

**Common tests to find out where CLL is in your body include:**

- **Imaging tests such as CT scans**—these are pictures of the inside of your body that help show where CLL is
How do I know how advanced my CLL is?

Your doctor may talk about your CLL as being a certain stage. Stages are a way for your healthcare team to talk about how advanced your cancer is. Your stage is based on how many CLL cells you have and where they are in your body. This translates into early, intermediate, or advanced CLL.

**Staging and the presence of symptoms often help your medical team determine:**

1) if treatment is necessary at this time, and
2) what the most appropriate treatment is
## 5 stages of chronic lymphocytic leukemia

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| **Intermediate** | I  • High lymphocyte count in the blood  
   • Swollen lymph nodes                                                   |
|            | II  • High lymphocyte count in the blood  
   • Swollen spleen or liver  
   • With or without swollen lymph nodes                                   |
| **Advanced** | III • High lymphocyte count in the blood  
   • Low red blood cell count (anemia)  
   • With or without swollen lymph nodes, spleen, or liver                  |
|            | IV  • High lymphocyte count in the blood  
   • Too few blood platelets  
   • With or without anemia or swollen lymph nodes, spleen, or liver       |

For definitions of certain medical terms, please see the Glossary on pages 24 and 25.
What are the goals of treatment?

There is no cure for CLL. As a result, the goals of treatment are to relieve symptoms, stop the cancer from getting worse, or achieve remission.

Treatment goals and options depend on how much your symptoms are affecting you:

- **When you don’t have symptoms**, close monitoring is usually preferred over treatment. This is often referred to as “watch and wait”
- **When symptoms appear or worsen**, treatment aims to stop the CLL from progressing

If your doctor says you need treatment, there are many options to help manage your CLL. CLL can be treated in a number of ways, including antibody therapy and/or chemotherapy. Often, doctors will combine the two types of treatment for better results.

Once you begin treatment, your doctor will need to regularly check your:

- Symptoms
- Size of lymph nodes, liver, or spleen
- Blood count measures
Antibody therapy

Antibody therapy is used to find and destroy specific cells within the body. It can use your body’s immune system to help fight cancer. It can also harm healthy cells in the body. It is often an important part of CLL treatment plans and can be given along with chemotherapy.

How it works
Antibody therapy targets a protein found on the surface of both CLL cells and some healthy blood cells. It is thought to use your body’s immune system to find and kill leukemia and healthy cells.

Chemotherapy

Chemotherapy is a drug treatment that destroys growing cells, including cancer cells. It is also an important part of CLL treatment plans. It can be given as a single drug or a combination of drugs including antibody therapy.

How it works
Chemotherapy attacks growing cancer cells in the body. It also attacks growing healthy cells in the body, such as those for hair and the intestinal lining.
About GAZYVA

What is GAZYVA?

GAZYVA® (obinutuzumab) is a type of antibody therapy that targets and attaches to the CD20 proteins found on CLL cells and some healthy blood cells.

Once attached to the CD20 protein, GAZYVA is thought to work in different ways, including:

- By helping your own immune system destroy the cancer cells
- By destroying the cancer cells directly

In addition, GAZYVA can harm healthy cells in your body.

Starting treatment with GAZYVA

On the days you receive GAZYVA, you should expect to spend most of the day at the clinic or infusion center. Your doctor may have you take medications one hour before you begin taking GAZYVA. Your doctor may refer to this kind of medication as premedication.

Common premedications include acetaminophen, antihistamines, and steroid medications. Taking the suggested medication before treatment may reduce the chance of possible side effects during your GAZYVA infusion. Be sure to check with your medical team about the proper premedication you should take before taking GAZYVA.
Please see pages 18-23 and accompanying full Prescribing Information for Important Safety Information, including BOXED WARNINGS.
How and when am I given GAZYVA?

GAZYVA® (obinutuzumab) is given as an infusion. This means it goes directly into your vein through a needle in your arm. You’ll get your treatment with GAZYVA at the clinic or infusion center.

GAZYVA is given for a total of 6 cycles, or rounds, of treatment. Each cycle will last 28 days. Treatment occurs only on certain days of each cycle, and that is usually followed by several weeks of rest and recovery. This means that most people will complete their GAZYVA treatment in about 6 months.

Each dose of GAZYVA is the same except for the first two days of Cycle 1. This is done to help reduce side effects you may have during the infusion. Some patients may have side effects during the infusion process. Please refer to page 17 for more information about these reactions.

Speak with your doctor if you miss a dose of GAZYVA.

GAZYVA® (obinutuzumab) is a prescription medicine used with the chemotherapy drug, chlorambucil, to treat chronic lymphocytic leukemia (CLL) in adults who have not had previous CLL treatment.
Below is the chart that shows when you should receive GAZYVA® (obinutuzumab).

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### CYCLES 2–6

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Speak with your doctor if you miss a dose of GAZYVA.

For Cycles 2 through 6, you will receive GAZYVA on the first day of each cycle (once every 28 days).

You should receive chlorambucil on Day 1 and Day 15 of Cycles 1 through 6.

Please see pages 18–23 and accompanying full Prescribing Information for Important Safety Information, including BOXED WARNINGS.
Preparing for your infusion

One week before:
- Tell your doctor about all the medicines you take, including prescription and non-prescription medicine, vitamins, and herbal supplements
- Speak to your doctor if you take medications to control your blood pressure. He/she may ask you to not take them on the day of your GAZYVA® (obinutuzumab) infusion
- Arrange a ride—after your infusion, you may feel drowsy or dizzy. It is a good idea to have someone else drive you home

One day before:
- Remember to follow any changes your doctor made to your regular medication schedule

The day of your infusion
At home:
- Wear or bring loose clothing so you can be comfortable during your infusion
- Pack food and drink—bringing some snacks or a packed meal can help you get through the day
- Bring a book or activities to help pass the time

At the clinic or infusion center:
- Take the medications prescribed by your doctor to help reduce the side effects of the infusion process
- Relax during your infusion, but be aware of what is happening to your body. Tell your doctor or nurse right away if you feel any side effects, including the symptoms of an infusion reaction
Infusion Reactions

These side effects may occur during or within 24 hours of any GAZYVA® (obinutuzumab) infusion. Some infusion reactions can be serious, including, but not limited to, severe allergic reactions (anaphylaxis), acute life-threatening breathing problems, or other life-threatening infusion reactions. If you have a reaction, the infusion is either slowed or stopped until your symptoms are resolved. Most patients are able to complete infusions and receive medication again. However, if the infusion reaction is serious, the infusion of GAZYVA will be permanently stopped. Your healthcare team will take steps to help lessen any side effects you may have to the infusion process. You may be given medicines to take before each GAZYVA treatment.

**Signs of infusion reactions may include:**

- Tiredness
- Dizziness
- Headache
- Redness of the face
- Nausea
- Chills
- Fever
- Vomiting
- Diarrhea
- Breathing problems
- Chest pain
Important safety information about GAZYVA

What is the most important safety information I should know about GAZYVA® (obinutuzumab)?
Tell your doctor right away about any side effect you experience. GAZYVA can cause side effects that can become serious or life threatening, including:

**Hepatitis B Virus (HBV)**
Hepatitis B can cause liver failure and death. If you have a history of hepatitis B infection, GAZYVA could cause it to return. You should not receive GAZYVA if you have active hepatitis B liver disease. Your doctor or healthcare team will need to screen you for hepatitis B before, and monitor you during and after, your treatment with GAZYVA. Sometimes this will require treatment for hepatitis B. Symptoms of hepatitis include: worsening of fatigue and yellow discoloration of skin or eyes.

**Progressive Multifocal Leukoencephalopathy (PML)**
PML is a rare and serious brain infection caused by a virus. PML can be fatal. Your weakened immune system could put you at risk. Your doctor will watch for symptoms. Symptoms of PML include: confusion, difficulty talking or walking, dizziness or loss of balance, and vision problems.

**Who should not receive GAZYVA?**
Do NOT receive GAZYVA if you have had an allergic reaction (eg, anaphylaxis or serum sickness) to GAZYVA. Tell your healthcare provider if you have had an allergic reaction to obinutuzumab or any other ingredients in GAZYVA in the past.

Please see accompanying full Prescribing Information for additional Important Safety Information, including BOXED WARNINGS.
What are the additional possible serious side effects of GAZYVA® (obinutuzumab)?
Tell your doctor right away about any side effect you experience. GAZYVA can cause side effects that may become severe or life threatening, including:

**Infusion Reactions**
These side effects may occur during or within 24 hours of any GAZYVA infusion. Some infusion reactions can be serious, including, but not limited to, severe allergic reactions (anaphylaxis), acute life-threatening breathing problems, or other life-threatening infusion reactions. If you have a reaction, the infusion is either slowed or stopped until your symptoms are resolved. Most patients are able to complete infusions and receive medication again. However, if the infusion reaction is serious, the infusion of GAZYVA will be permanently stopped. Your healthcare team will take steps to help lessen any side effects you may have to the infusion process. You may be given medicines to take before each GAZYVA treatment. Symptoms of infusion reactions may include: fast heartbeat, tiredness, dizziness, headache, redness of the face, nausea, chills, fever, vomiting, diarrhea, rash, high blood pressure, low blood pressure, difficulty breathing, and chest discomfort.

**Hypersensitivity Reactions Including Serum Sickness**
Some people receiving GAZYVA may have severe or life-threatening allergic reactions. This reaction may be severe, may happen during or after an infusion, and may affect many areas of the body. If an allergic reaction occurs, your doctor will stop the infusion and permanently discontinue GAZYVA.
Tumor Lysis Syndrome (TLS)
Tumor lysis syndrome, including fatal cases, has been reported in patients receiving GAZYVA® (obinutuzumab). GAZYVA works to break down cancer cells quickly. As cancer cells break apart, their contents are released into the blood. These contents may cause damage to organs and the heart, and may lead to kidney failure requiring the need for dialysis treatment. Your doctor may prescribe medication to help prevent TLS. Your doctor will also conduct regular blood tests to check for TLS. Symptoms of TLS may include nausea, vomiting, diarrhea, and tiredness.

Infections
While you’re taking GAZYVA, you may develop infections. Some of these infections may be fatal and severe, so be sure to talk to your doctor if you think you have an infection. Patients with a history of recurring or chronic infections may be at an increased risk of infection. Patients with an active infection should not be treated with GAZYVA.

Low White Blood Cell Count
When you have an abnormally low count of infection-fighting white blood cells, it is called neutropenia. While you are taking GAZYVA, your doctor will do blood work to check your white blood cell count. Severe and life-threatening neutropenia can develop during or after treatment with GAZYVA. Some cases of neutropenia can last for more than one month. If your white blood cell count is low, your doctor may prescribe medication to help prevent infections.
Low Platelet Count
Platelets help stop bleeding or blood loss. GAZYVA® (obinutuzumab) may reduce the number of platelets you have in your blood; having low platelet count is called thrombocytopenia. This may affect the clotting process. While you are taking GAZYVA, your doctor will do blood work to check your platelet count. Severe and life-threatening thrombocytopenia can develop during or after treatment with GAZYVA. If your platelet count gets too low, your treatment may be delayed or reduced.

The most common side effects of GAZYVA are infusion reactions, low white blood cell counts, low platelet counts, low red blood cell counts, fever, cough, nausea, and diarrhea.

What other information should I tell my doctor before receiving GAZYVA?
You should talk to your doctor about:

Immunizations
Before receiving GAZYVA therapy, tell your healthcare provider if you have recently received or are scheduled to receive a vaccine. People who are treated with GAZYVA should not receive live vaccines.

Pregnancy
Tell your doctor if you are pregnant, think that you might be pregnant, plan to become pregnant, or are breastfeeding. GAZYVA may harm your unborn baby. Speak to your doctor about using GAZYVA while you are pregnant. Talk to your doctor or your child’s doctor about the safety and timing of live virus vaccinations to your infant if you received GAZYVA during pregnancy. It is not known if GAZYVA may pass into your breast milk. Speak to your doctor about using GAZYVA if you are breastfeeding.
Most common side effects

**Side effects in a clinical trial**

The following side effects have occurred with GAZYVA® (obinutuzumab) infusions:

- **Infusion reactions**
  - First 2 days of treatment – 65%
  - Later infusions – 3%
- **Low counts of certain cells within the blood**
  - White blood cells – 38%
  - Platelets – 14%
  - Red blood cells – 11%
- **Fever** – 10%
- **Cough** – 10%
- **Nausea** – 12%
- **Diarrhea** – 10%

Please see accompanying full Prescribing Information for additional Important Safety Information, including BOXED WARNINGS.
Tell your doctor about any side effects.

These are not all of the possible side effects of GAZYVA® (obinutuzumab). For more information, ask your doctor or pharmacist.

GAZYVA is available by prescription only.

You may report side effects to the FDA at (800) FDA-1088, or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

Please see the accompanying full Prescribing Information, including BOXED WARNINGS, for additional Important Safety Information.

Remember to tell your healthcare team exactly how you feel. This will allow them to take the proper actions to help you.
**Glossary**

**Anemia:** Having too few red blood cells in the body. This can cause a person to feel tired, weak, and short of breath because the tissues are not getting enough oxygen.

**Antibody therapy:** A type of therapy used to find and destroy specific cells within the body (for example, the cells where CLL starts). Antibody therapy can also harm healthy cells in the body. This is a type of immunotherapy.

**Bone marrow:** The soft spongy material that fills the inside of bones. Bone marrow is the source of new blood cells, and platelets are made in the bone marrow.

**Chemotherapy:** A drug treatment that destroys fast-growing cells, including cancer cells.

**Chronic lymphocytic leukemia (CLL):** One type of blood cancer or leukemia. With CLL, the blood or bone marrow has too many white blood cells, known as lymphocytes.

**CT (computed tomography) scan:** A medical test that uses a computer linked to an x-ray machine to take pictures of the inside of the body.

**Flow cytometry:** This test identifies the type of blood cancer and number of cells involved.

**Immune cells:** Cells that defend the body from infection. These cells are part of the immune system.

**Immune system:** The group of organs and cells that defends the body from infections.

**Immunotherapy:** A treatment (such as antibodies) that uses your body’s immune system to help fight cancer. Immunotherapy can also harm healthy cells in the body.

**Leukemia:** A cancer of white blood cells.

**Lymph node:** A small bean-shaped organ that stores white blood cells.
**Lymphocytes**: A type of white blood cell that has an important role in fighting infection.

**Platelet**: A type of cell found in the blood and spleen. Platelets help prevent bleeding by forming blood clots.

**Relapse**: A term used to describe the return of disease after it has responded to treatment.

**Remission**: A term used to describe a response to treatment. Partial remission means the cancer is significantly improved, but evidence of the cancer remains. Complete remission means all evidence of the cancer is gone for a period of time.

**Spleen**: An organ that is part of the lymphatic system. The spleen makes lymphocytes, filters blood, stores blood cells, and destroys old blood cells. It is located on the left side of the abdomen near the stomach.

**Watch and wait**: A period of time when patients, along with their doctor, watch the disease and do not start treatment unless needed.
Support and resources

Support from Genentech

Genentech BioOncology® Co-pay Card Program
The Genentech BioOncology® Co-pay Card program helps people with commercial health insurance. This might be a plan you get through your employer or one you purchased through a Health Insurance Marketplace like HealthCare.gov. To qualify, you must also meet other criteria.

Independent Co-pay Assistance Foundations
If you need help with your co-pay for your Genentech medicine, GAZYVA Access Solutions can refer you to an independent co-pay assistance foundation. Independent co-pay assistance foundations help patients with public health insurance or commercial health insurance.

The Genentech® Access to Care Foundation (GATCF)
GATCF helps people who don’t have health insurance. It also helps people who have health insurance but have trouble paying for GAZYVA. If you qualify for GATCF, you could receive your medicine for free.

To learn more about how we can help,
CALL 1 866-422-2377
VISIT www.genentech-access.com/GAZYVA/patients
Helpful resources

Many patient support groups offer helpful information about cancer. Some may also help you connect with a local support group. You can share your experiences and learn more about CLL. Many people find this helps them stay informed and stay positive.

Cancer organizations
American Cancer Society
1-800-ACS-2345 (1-800-227-2345)
www.cancer.org

CancerCare, Inc.
1-800-813-HOPE (1-800-813-4673)
www.cancercare.org

National Cancer Institute
1-800-4-CANCER (1-800-422-6237)
www.cancer.gov

National Comprehensive Cancer Network
www.nccn.org/patients

Leukemia organizations
Lymphoma Research Foundation
1-800-500-9976
www.lymphoma.org

The Leukemia & Lymphoma Society
1-800-955-4572
www.lls.org

Support organizations
Cancer Support Community
1-888-793-WELL (1-888-793-9355)
www.cancersupportcommunity.org

Patient Advocate Foundation
1-800-532-5274
www.patientadvocate.org

Genentech is not affiliated with any of these organizations. The information provided by Genentech or these organizations is meant for informational purposes only. It is not meant to replace your physician’s medical advice.
Questions to ask your doctor

Before starting treatment, it is important to ask your doctor or nurse any questions you may have. It is a good idea to write down a list of questions before your appointment. Bring a family member or friend to your appointment for support. They can also help you keep track of the answers.

Here are some questions to consider asking:

• What are my treatment options?
• What will my treatment schedule be?
• Do I need to take medication at home as well?
• What are the possible side effects of treatment?
• Is there more I can do to make the most of my treatment?
• Where can I find information about support to help me pay for my GAZYVA® (obinutuzumab) therapy?
• Where can I get more information about CLL?
• How will treatment with GAZYVA affect my lifestyle (working, traveling, etc)?
Use this space to help keep track of important contact information.

**Doctor** (Name): ____________________________

__________  ____________

**Nurse** (Name): ____________________________

__________  ____________

**Hospital** (Name): ____________________________

__________  ____________

**Pharmacy** (Name): ____________________________

__________  ____________

**Emergency** (Name): ____________________________

__________  ____________
Use this space to write down additional information or questions.

Notes: __________________________________________________________

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