Obinutuzumab and Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (CHOP)

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is used for follicular lymphoma (FL).
- It may also be used for other reasons.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

This treatment is often called Obinutuzumab and CHOP:

- **C**: Cyclophosphamide
- **H**: Hydroxydaunorubicin (Doxorubicin)
- **O**: Oncovin (Vincristine)
- **P**: Prednisone

Treatment Name	How the Treatment Works	How the Treatment is Given
Obinutuzumab (OH-bin-yoo-TOO-zoo-mab): Gazyva (guh-ZY-vuh)	Helps your immune system find and attack cancer cells by targeting a specific protein on their surface.	Infusion into a vein (intravenous (IV) infusion).
Cyclophosphamide (SY-kloh-FOS-fuh-mide): Cytoxan (sai-TAAK-sn)	Slows down or stops the growth of cancer cells by damaging the genetic material that cancer cells need to multiply. It can also be used to dull the immune response.	Infusion into a vein (intravenous (IV) infusion).
Doxorubicin (DOK-soh-ROO-bih-sin): Adriamycin (AY-dree-uh-MY-sin), Hydroxydaunorubicin (hy-DROK-see-DAW-noh-ROO-bih-sin)	Slows down or stops the growth of cancer cells by damaging the genetic material that cancer cells need to grow.	Infusion into a vein (intravenous (IV) infusion).
Vincristine (vin-KRIS-teen): Oncovin (ON-koh-vin)	Slows down or stops the growth of cancer cells by preventing cancer cells from properly dividing and creating new cells.	Infusion into a vein (intravenous (IV) infusion).
Prednisone (PRED-nih-sone)	Tells cancer cells to "self-destruct".	Tablet(s) taken by mouth.

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Treatment Administration and Schedule

Treatment is typically repeated every 21 days. This length of time is called a "cycle." Your treatment typically has 2 parts: induction and maintenance. You may receive up to 6 cycles with obinutuzumab and CHOP, followed by treatment with obinutuzumab alone. Your care team will tell you how many treatment cycles you will receive and how long you will continue taking obinutuzumab.

Note: Prednisone is taken by mouth 1 time each day on Days 1 to 5 of cycles 1 to 6.

- Your care team will prescribe this medicine.
- Take prednisone with food to avoid stomach upset.
- Tell your care team if you develop heartburn or acid reflex.
- Prednisone may increase your blood sugar and blood pressure on days of therapy.
- Avoid taking it in the evening (after 6 PM) or before bedtime, as it can cause trouble sleeping.

Induction (Cycle 1)

- Obinutuzumab is given on Days 1, 8, and 15.
- Cyclophosphamide is given on Day 1.
- Doxorubicin is given on Day 1.
- Vincristine is given on Day 1.
- Prednisone is taken on Days 1 to 5.

Treatment Name	Induction: Cycle 1																
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15	…	Day 21
Treatment Given at the Clinic or Hospital																	
Obinutuzumab	✓							✓							✓		
Cyclophosphamide	✓																
Doxorubicin	✓																
Vincristine	✓																
Treatment Taken at Home																	
Prednisone	✓	✓	✓	✓	✓												

Induction (Continued) (Cycles 2 to 6)

- Obinutuzumab is given on Day 1.
- Cyclophosphamide is given on Day 1.
- Doxorubicin is given on Day 1.
- Vincristine is given on Day 1.
- Prednisone is taken by mouth 1 time each day on Days 1 to 5.

Treatment Name	Cycle 2								Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	…	Day 21	Day 1
Treatment Given at the Clinic or Hospital									
Obinutuzumab	✓								✓
Cyclophosphamide	✓								✓
Doxorubicin	✓								✓
Vincristine	✓								✓
Treatment Taken at Home									
Prednisone	✓	✓	✓	✓	✓				✓

Maintenance (Cycles 7 and 8)

- Obinutuzumab is given on Day 1 every 21 days.

Treatment Name	Cycle 7								Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	…	Day 21	Day 1
Obinutuzumab	✓								✓

Optional Maintenance

- Obinutuzumab is given on Day 1 every 8 weeks.

Treatment Name	Maintenance Cycle								Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	…	Day 56	Day 1
Obinutuzumab	✓								✓

Appointments

Appointments may include regular check-ups with your care team, treatment appointments, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss an appointment, call your care team as soon as possible to reschedule it.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Given at the Clinic or Hospital	Supportive Care Taken at Home
To help your body make white blood cells to fight infections		
To help lower the risk of infections		
To help lower the risk of infusion-related reactions		
To help prevent or treat nausea and vomiting		
To help prevent tumor lysis syndrome (TLS)		
Other		

Common Side Effects

Side Effect	Important Information
Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection (Boxed Warning)	Description: WBCs help protect your body from infections. A low WBC count increases your risk of infection. Recommendations: • Wash your hands often and bathe regularly. • Avoid crowded places and close contact with people who are sick. • Follow food safety and wound care advice from your care team. • Your care team may prescribe medicine to help your WBCs recover. Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Chills • New or worsening cough or sore throat • Painful urination or signs of a urinary infection • Feeling much more tired than usual • Red, swollen, warm, or painful areas on the skin (possible skin infection)
Low Platelet Count (Thrombocytopenia) (Boxed Warning)	Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding. Recommendations: • Blow your nose gently and avoid picking it. • Brush your teeth gently with a soft toothbrush and keep good oral hygiene. • Use an electric razor for shaving and a nail file instead of nail clippers. • Avoid over-the-counter medicines that can increase bleeding risk (for example, nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen). • Talk with your care team or dentist before medical or dental procedures — you may need to pause treatment. Talk to your care team if you have: • A nosebleed lasting more than 5 minutes despite pressure • A cut that continues to bleed • Heavy gum bleeding when brushing or flossing • Sudden or severe headache • Blood in your urine or stool • Blood in your spit after coughing
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia) (Boxed Warning)	Description: RBCs and Hgb carry oxygen to your body's tissues and remove carbon dioxide. Low RBC or Hgb (anemia) can make you feel weak or very tired, or may make you look pale. Recommendations: • Aim for 7 to 8 hours of sleep each night. • Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. • Balance activity and rest — stay as active as you can, but rest when needed. • Eat a balanced diet and follow any nutrition or supplement advice from your care team. Talk to your care team if you have: • Shortness of breath • Dizziness or fainting • Fast or irregular heartbeats • Sudden or severe headache

Liver Problems	Description: Treatment can cause liver injury. Your care team may check your liver with blood tests before and during treatment. Talk to your care team if you have: • Yellowing of your skin or the white part of your eyes (jaundice) • Severe nausea or vomiting • Pain on the right side of your stomach area (abdomen) • Dark, tea-colored urine • Bleeding or bruising more easily than normal
Constipation	Description: Constipation means hard, dry stools or fewer bowel movements than normal. It can cause discomfort or pain. Recommendations: • Track how often you have bowel movements each day. • Drink 8 to 10 glasses of fluids daily, unless your care team says otherwise. • Stay active and exercise regularly. • Eat more high-fiber foods (such as raw fruits, vegetables, and whole grains) unless advised otherwise. • Your care team may recommend laxatives such as polyethylene glycol (MiraLAX) or senna. Talk to your care team if you have: • Constipation lasting 3 or more days • No bowel movement 48 hours after using a laxative
Diarrhea	Description: Diarrhea is loose, watery stools or more frequent bowel movements than usual. It can cause dehydration and weakness. Recommendations: • Keep track of how often you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids daily, unless your care team tells you otherwise. • Eat small meals of mild, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). • If you have diarrhea, avoid high-fiber foods (such as raw vegetables, fruits, and whole grains), gas-producing foods (such as broccoli and beans), dairy (such as milk and yogurt), and spicy, fried, or greasy foods. • Your care team may recommend an antidiarrheal medicine such as loperamide (Imodium). Talk to your care team if you have: • 4 or more bowel movements above your usual number in 24 hours • Dizziness or lightheadedness while having diarrhea • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Bloody diarrhea

Cough	Description: A cough is a reflex action that forcefully expels air from the lungs to clear the airways of irritants or mucus. Recommendations: • Tell your care team what your cough feels like and when it happens. • Use a humidifier and drink plenty of water. • Keep your house clean by dusting and vacuuming regularly • Avoid exposure to smoke or strong chemicals. • Your care team may recommend medicine for cough. Talk to your care team if you have: • Trouble breathing • Chest pain or tightness • Coughing up blood
Infusion-Related Reactions	Description: An infusion reaction is a bad response that can happen during or shortly after receiving medicine through a vein. Recommendations: • Your care team may prescribe medicines before your infusion to help reduce your risk of infusion reactions or make any infusion reaction less severe. • You may be monitored for infusion reactions during each infusion. • Your care team may slow down or stop your infusion, or completely stop treatment if you have an infusion reaction. Get medical help right away if you develop any of the following during or after your infusion: • Chills or shaking • Itching, rash, or flushing • Trouble breathing, wheezing, or tongue swelling • Dizziness or feeling faint • Feeling of impending doom • Fever of 100.4°F (38°C) or higher • New or severe pain in your back or neck
Changes in Electrolytes and Other Laboratory Results (Hypophosphatemia, Hypoproteinemia, Hypocalcemia	Description: Treatment may cause low levels of phosphate, protein, and calcium in your blood. Your care team will perform blood tests to check for these changes and will treat you if needed. Talk to your care team if you have: • New or worsening muscle weakness, cramps, or bone pain • Trouble breathing or shortness of breath • Confusion, slurred speech, or severe dizziness • Severe fatigue or inability to perform daily activities • Fatigue • Thinning, dry hair or dry skin • Muscle stiffness, weakness, or muscle spasms • Numbness or tingling in your fingers, toes, or around your mouth • Seizures • Sudden weight gain • Swelling of your arms, hands, legs, and ankles

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Hepatitis B Virus (HBV) Reactivation (Boxed Warning)	Before you receive obinutuzumab, your care team will do blood tests to check for HBV infection. If you have had hepatitis B or are a carrier of hepatitis B virus, receiving obinutuzumab could cause the virus to become an active infection again. Hepatitis B reactivation may cause serious liver problems, including liver failure and death. Your care team will monitor you for hepatitis B infection during and for several months after you stop receiving obinutuzumab. • Worsening tiredness • Yellowing of your skin or white part of your eyes
Progressive Multifocal Leukoencephalopathy (PML) (Boxed Warning)	PML is a rare, serious brain infection caused by a virus that can happen in people who receive obinutuzumab. People with weakened immune systems can get PML. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML. • Confusion • Dizziness or loss of balance • Difficulty walking or talking • Decreased strength or weakness on one side of your body • Vision problems, such as blurred vision or loss of vision
Heart Problems (Boxed Warning)	Doxorubicin may cause heart problems that may lead to death. These problems can happen during your treatment or months to years after stopping treatment. In some cases, heart problems are irreversible. There is a cumulative total lifetime dose of doxorubicin. Your care team will track the amount of doxorubicin you receive. Talk with your care team if you have received anti-cancer medicines before. Your care team will perform tests to check your heart before, during, and after your treatment with doxorubicin. • Swelling of your stomach-area (abdomen), legs, hands, feet, or ankles • Shortness of breath • Nausea or vomiting • New or worsening chest discomfort, including pain or pressure • Weight gain • Pain or discomfort in your arms, back, neck, or jaw • Protruding neck veins • Breaking out in a cold sweat • Feeling lightheaded or dizzy
Bone Marrow Problems called Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML) (Boxed Warning)	Symptoms of low blood cell counts are common during treatment, but can be a sign of serious bone marrow problems, including MDS or AML. Symptoms may include: • Weakness • Weight loss • Fever • Frequent infections • Blood in urine or stool • Shortness of breath • Feeling very tired • Bruising or bleeding more easily

Extravasation (Boxed Warning)	Extravasation happens when medicine that is supposed to go into a vein leaks out into the tissues around it. This can cause pain, swelling, and damage to the skin and tissues. Doxorubicin and vincristine may cause extravasation. • Pain, burning, or stinging at the infusion site • Swelling, redness, or blistering around the site • Coolness or numbness in the area • Decreased blood flow or tissue damage, potentially leading to ulcers or tissue death in severe cases
Change in the Color of Your Urine	You may have red- or orange-colored urine for 1 to 2 days after your infusion of doxorubicin. This is normal. • Your urine remains red- or orange-colored after a few days • Blood or blood clots in your urine
Disseminated Intravascular Coagulation (DIC)	DIC is a serious condition where clotting and bleeding happen at the same time. Small clots use up clotting factors and platelets, which can lead to uncontrolled bleeding and organ problems. • Heavy or uncontrolled bleeding (nosebleed, mouth bleeding, or bleeding from a wound) • Many new or worsening bruises • Blood in your urine or stool, or coughing up blood • Sudden shortness of breath, chest pain, or fast/irregular heartbeat • Confusion, sudden weakness, or difficulty speaking • Little or no urine output or severe abdominal pain
Kidney Problems	• Decrease in your amount of urine • Blood in your urine • Swelling of your ankles • Loss of appetite
Bladder Irritation (Hemorrhagic Cystitis)	Cyclophosphamide can cause irritation and damage to your bladder. To reduce this risk, drink plenty of fluids and urinate frequently for a few days after each dose of cyclophosphamide. • Blood in the urine • Painful urination • Urinating more frequently • Stomach (abdominal) or pelvic pain • Fever of 100.4°F (38°C) or higher
Lung Problems	• Cough • Shortness of breath • Chest pain or tightness

Hormone Gland Problems	• Headaches that will not go away, or unusual headaches • Eye sensitivity to light • Eye problems • Rapid heartbeat • Increased sweating • Extreme tiredness • Weight gain or weight loss • Feeling more hungry or thirsty than usual	• Urinating more often than usual • Hair loss • Feeling cold • Constipation • Your voice gets deeper • Dizziness or fainting • Changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
Skin Problems	• Rash • Itching	• Skin blistering or peeling • Painful sores or ulcers in the mouth or nose, throat, or genital area
Problems in Other Organs and Tissues	• Chest pain, irregular heartbeat, shortness of breath, swelling of ankles • Confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs	• Double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight • Persistent or severe muscle pain or weakness, muscle cramps • Low red blood cells, bruising
Tumor Lysis Syndrome (TLS)	Tumor lysis happens when cancer cells break apart and release large amounts of substances into your bloodstream faster than your body can handle. TLS is a group of conditions that affect your heart, kidneys, and muscles. • Severe nausea, vomiting, or diarrhea • Urinating smaller amounts or having dark-colored urine • Muscle cramps or twitching	• Rapid heartbeats or chest pain • Confusion or weakness • Seizures
Allergic Reactions and Serum Sickness	Serum sickness is a delayed allergic reaction that can happen days to weeks after treatment. Get emergency medical help right away if you develop any of the following signs or symptoms: • Swelling of your lips, mouth, tongue, or throat • Trouble breathing or swallowing • Raised red areas on your skin (hives) • A very fast heartbeat	• You feel dizzy or faint • Chest pain or tightness • Fever of 100.4°F (38°C) or higher • Joint pain or stiffness

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Fertility, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body.** However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment can affect your **ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- Treatment may **harm an unborn baby**.
    - If you are able to become pregnant:
        - Your care team will verify your pregnancy status before treatment.
        - Use an effective method of birth control during treatment with obinutuzumab and CHOP, for 6 months after your last dose of obinutuzumab and doxorubicin, and for 1 year after your last dose of cyclophosphamide.
        - If you think you might be pregnant or if you become pregnant, tell your care team right away.
    - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment with obinutuzumab and CHOP, for 10 days after your last dose of doxorubicin, for 4 months after your last dose of cyclophosphamide, and for 6 months after your last dose of obinutuzumab.
- **Do not breastfeed** during treatment with obinutuzumab and CHOP, for 1 week after your last dose of cyclophosphamide, for 10 days after your last dose of doxorubicin, and for 6 months after your last dose of obinutuzumab. It is **not known** if vincristine is present in **breast milk**.

Handling Body Fluids and Waste

Some drugs you receive may stay in your urine, stool, sweat, or vomit for many days after treatment. Because many cancer drugs are toxic, your body waste may also be dangerous to touch. To help protect yourself, your loved ones, and the environment, **follow these instructions** for at least **48 hours** after each dose of **cyclophosphamide,** at least **7 days** after each dose of **doxorubicin,** and at least **3 weeks** after each dose of **vincristine**: (Note: Obinutuzumab and prednisone do not require special handling of body fluids and waste.)

- People who are pregnant should avoid touching anything that may be soiled with body fluids from the patient.
- You can use your usual toilet. Always close the lid and flush to discard all waste. If you have a low-flow toilet, flush twice.
- If the toilet or seat is soiled with urine, stool, or vomit, clean the surface after each use before others use it.
- Wash your hands with soap and water for at least 20 seconds after using the toilet.
- If you need a bedpan, inform your caregiver so they can wear gloves and assist with cleanup. Wash the bedpan with soap and water daily.
- If you cannot control your bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb waste.
- Wash any skin exposed to body waste with soap and water.
- Wash soiled linens or clothing separately from other laundry. If you don’t have a washer, place them in a plastic bag until they can be washed.
- Wash your hands with soap and water after touching soiled linens or clothing.

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Additional Information

- **Tell your care team about all the medicines you take**.
  This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **You should not receive a "live vaccine"** before, during, or after treatment, until your care team tells you it is okay. If you are not sure about the type of immunization or vaccine, ask your care team. These vaccines may not be safe or may not work as well during treatment.
- **Wound healing problems**. Wounds may not heal properly during cyclophosphamide treatment. Tell your care team if you plan to have any surgery before starting or during treatment with cyclophosphamide.
- **This Patient Education Sheet may not describe all possible side effects.**
  Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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